IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: All cases	

MASTER LONG-FORM COMPLAINT AND JURY DEMAND

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Plaintiffs, by and through their counsel, for their Master Long Form Complaint ("Master Complaint") against Defendants AbbVie Inc., Abbott Laboratories, AbbVie Products LLC, Unimed Pharmaceuticals, LLC, Solvay, S.A., Besins Healthcare Inc., Besins Healthcare, S.A., Eli Lilly and Company, Lilly USA, LLC, Acrux Limited, Acrux DDS Pty Ltd., Endo Pharmaceuticals, Inc., Auxilium Pharmaceuticals, Inc., GlaxoSmithKline plc, Pfizer, Inc., Pharmacia & Upjohn Company, Inc., Actavis plc, Actavis, Inc., Actavis Pharma, Inc., Actavis Laboratories UT, Inc., Watson Laboratories, Inc., and Anda, Inc. (collectively, "Defendants"), allege on personal knowledge as to themselves, and on information and belief as to all other matters, as follows:

NATURE OF THIS MASTER COMPLAINT

1. This Master Complaint sets forth questions of fact and law common to those claims subsumed within the context of this multidistrict proceeding for claims relating to testosterone replacement therapy products ("TRT products" or "TRTs"). It includes allegations involving nine different products manufactured sold, distributed, and promoted by six sets of defendants, although not all products and defendants are applicable to every plaintiff with claims in these proceedings. Plaintiffs seek compensatory and punitive damages, monetary restitution, equitable relief, and all other available remedies as a result of injuries incurred by Defendants' defective products.

2. This Master Complaint does not necessarily include all claims asserted in all of the transferred actions to this Court, nor is it intended to consolidate for any purpose the separate claims of the Plaintiffs herein. It is anticipated that individual plaintiffs may adopt this Master Complaint and the necessary causes of action herein through use of a separate Master Short Form Complaint for Individual Claims, which will specify the particular products and defendants against whom claims are asserted by that individual plaintiff. (The form of the Master Short Form Complaint for Individual Claims is attached hereto as Exhibit A.) Any separate facts and additional

claims of individual plaintiffs are set forth in those actions filed by the respective plaintiffs.

3. This Master Complaint does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, nor does any Plaintiff relinquish the right to move to amend their individual claims to seek any additional claims as discovery proceeds. As more particularly set forth herein, each Plaintiff maintains that TRTs are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lacked proper warnings of the dangers associated with their use.

NATURE OF THE ACTION

4. Plaintiffs in these actions seek compensation for injuries resulting from use of defective prescription TRT products manufactured, sold, distributed and promoted by Defendants.

5. TRTs were approved for use in the treatment of a medical condition known as hypogonadism, but widely marketed by Defendants for off-label use for a condition invented by Defendants and referred to as "Low T" (a reference to low testosterone). Defendants marketed TRTs as safe and effective for this off-label use, when in fact (a) TRTs confer little or no benefit for so-called "Low T" in the absence of "classical hypogonadism"; and (b) the drugs cause serious medical problems, including life threatening cardiac, cerebrovascular, and thromboembolic events, for which Defendants failed to provide adequate warnings.

6. The nine TRT products at issue in this litigation are: AndroGel, Axiron, Fortesta, Delatestryl, Testim, Testopel, Striant, Depo-Testosterone, and Androderm. With respect to each of these products, Defendants exaggerated their benefits and understated, omitted and/or failed adequately to warn patients and physicians about the risks associated with such products and the monitoring required to ensure patient safety.

7. Defendants engaged in aggressive, award-winning direct-to-consumer ("DTC") and physician marketing and advertising campaigns for TRT products. Further, Defendants also engaged in aggressive unbranded "disease awareness" campaigns to alert men that they might be suffering from "Low T," an abbreviated term for low testosterone and a "condition" invented by Defendants.

8. According to the industry-leading Androgen Deficiency in Adult Males ("ADAM") or "Is it Low T?" quiz, the symptoms of "Low T" include being "sad or grumpy," "experiencing deterioration in the ability to play sports," and "falling asleep after dinner." In fact, most doctors agree that these symptoms can be caused by an abundance of factors, the most prominent of which is the natural aging process.

9. The FDA has not approved any TRT product as a treatment for low testosterone or "Low T." Indeed, "Low T" is not a disease recognized by the medical community. Instead, it is a normal result of the aging process experienced by the majority of males.

10. As a result of this "disease mongering," as termed by Dr. Adriene Fugh-Berman of Georgetown University Medical Center, diagnoses of "Low T" – and prescriptions for TRTs -- have increased exponentially.

11. Consumers of TRT products and their physicians relied on Defendants' false representations and were misled as to TRT products' safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thromboembolic events.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 as to the claims of the respective Plaintiffs.

13. The amount in controversy alleged by each of the respective individual Plaintiffs will exceed seventy-five thousand dollars ($75,000.00).

PARTIES

Plaintiffs

14. This Master Complaint is filed on behalf of all Individual Injured Plaintiffs ("Plaintiffs") whose claims are subsumed within MDL No. 2545. Plaintiffs in these individual actions have suffered personal injuries as a result of the use of TRT products. In addition, and where applicable, this Master Complaint is also filed on behalf of Plaintiffs' spouses, children, parents, decedents, wards and/or heirs, all as represented by Plaintiffs' counsel.

15. Plaintiffs have suffered personal injuries as a direct and proximate result of Defendants' conduct and misconduct as described herein and in connection with, inter alia, the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of their respective TRT products.

16. Plaintiffs file these lawsuits within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiffs. Plaintiffs could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiffs' injuries as their cause was unknown to Plaintiffs. Plaintiffs did not suspect, nor did Plaintiffs have reason to suspect, that Plaintiffs had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of these actions. Additionally, Plaintiffs were prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that TRT drugs are safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiffs to discover potential causes of action.

Defendants

The AbbVie Defendants

17. Defendant AbbVie Inc. is a corporation organized and existing under the

laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Lake County, Illinois 60064.

18. Defendant Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois and maintains its principal place of business at 100 Abbott Park Road, North Chicago, Lake County, Illinois 60064.

19. Defendant AbbVie Products LLC f/k/a Solvay Pharmaceuticals, Inc. ("AbbVie Products") is incorporated in the State of Georgia and has its principal place of business at 1 North Waukegan Road, North Chicago, Illinois, 60064.

20. AbbVie Products is a wholly-owned subsidiary of Defendant AbbVie Inc. AbbVie Products is the parent company of Defendant Unimed Pharmaceuticals, LLC.

21. Defendant Unimed Pharmaceuticals, LLC f/k/a Unimed Pharmaceuticals, Inc. ("Unimed") is a limited liability company organized and existing under the laws of Delaware, with its headquarters and principal place of business at 1 North Waukegan Road, North Chicago, Illinois, 60064.

22. Unimed is a wholly-owned subsidiary of Defendant AbbVie Inc. and a direct, wholly-owned subsidiary of Defendant AbbVie Products.

23. Unimed is the registered owner of the trademark for AndroGel that is registered with the United States Patent and Trademark Office.

24. Defendant Solvay, S.A. ("Solvay") is a Belgian corporation with its principal place of business at Rue du Prince Albert 33, B-1050 Brussels - Belgium. At all relevant times, Solvay S.A. has conducted extensive business throughout the United States. At relevant times, Solvay S.A. was the ultimate parent company of Solvay Pharmaceuticals, Inc. n/k/a Defendant AbbVie Products LLC.

25. Besins Healthcare Inc. f/k/a Besins-Iscovesco U.S., Inc. ("Besins Inc.") is a corporation organized and existing under the laws of the State of Delaware. Besins Healthcare Inc. has its principal place of business at 607 Herndon Parkway, Suite 210, Herndon, Virginia 20170. Besins Healthcare Inc. is a wholly-owned subsidiary of Besins

Healthcare, S.A.

26. Besins Healthcare, S.A. f/k/a Laboratoires Besins-Iscovesco, S.A. ("Besins S.A.") is a privately held corporation with its headquarters in Bangkok, Thailand, at the following address: Besins Healthcare, S.A., 283/92 Home Place Office Building, 18th Floor Sukhumvit 55, Klong Ton Nua Wattana, Bangkok 10110, Thailand. Besins Healthcare, S.A. developed the pharmaceutical formulation for AndroGel in collaboration with Unimed. At all relevant times, Besins S.A. has conducted extensive business throughout the United States.

27. At all relevant times Besins S.A. and Besins Inc. owned rights to sell AndroGel in the United States. At all relevant times, Besins S.A. manufactured AndroGel for sale in the United States.

28. Together, AbbVie Inc., Abbott Laboratories, AbbVie Products, Unimed, Solvay, Besins Inc. and Besins S.A. are referred to in this Master Complaint as "AbbVie."

29. AbbVie is sued herein in connection with its TRT product, AndroGel.

The Lilly Defendants

30. Defendant Eli Lilly and Company is a corporation organized and existing under the laws of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

31. Defendant Lilly USA, LLC. is a limited liability company operating as a wholly-owned subsidiary of Defendant Eli Lilly and Company, with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

32. Together, Eli Lilly and Company, and Lilly USA, Inc. are referred to in this Master Complaint as "Lilly."

33. Lilly is sued herein in connection with its TRT product, Axiron.

34. Defendant Acrux Limited is a foreign corporation organized and existing under the laws of Australia, with its principal place of business at 103-113 Stanley

Street, West Melbourne VIC 3003, Australia.

35. Acrux DDS Pty Ltd. is a foreign corporation organized and existing under the laws of Australia, with its principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux DDS Pty Ltd. is a wholly owned subsidiary of Acrux Limited.

36. Together, Acrux Limited and Acrux DDS Pty Ltd. are referred to in this Master Complaint as "Acrux."

37. At all times relevant, Acrux was engaged in the research, development, manufacture, sales, marketing, and/or distribution of pharmaceutical products, including Axiron, in the State of Illinois and is therefore subject to the jurisdiction and venue of the State of Illinois. Acrux has conducted business in and derived substantial revenue from sales of Axiron within the State of Illinois.

38. Acrux originally developed Axiron and still owns the intellectual property right to it. Acrux DDS Pty Ltd. owns the patents for Axiron. Acrux is thus also sued in connection with that product.

Endo, Auxilium, and GSK

39. Defendant Endo Pharmaceuticals, Inc. ("Endo") is a corporation organized and existing under the laws of Delaware with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

40. Defendant Auxilium Pharmaceuticals, Inc. ("Auxilium") is a corporation organized and existing under the laws of the State of Delaware, with headquarters and a principle place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087.

41. On or about January 29, 2015, Endo (directly or indirectly) acquired Auxilium. Auxilium owned, manufactured, marketed, and sold three TRT products, Testim, Testopel, and Striant. In acquiring Auxilium, Endo assumed all liabilities arising from those three products.

42. Endo is sued herein in connection with its two original TRT products

Fortesta and Delatestryl, and also in connection with the three products it acquired from Auxilium, Testim, Testopel, and Striant. To the extent that any of Auxilium's liabilities were not assumed, and to the extent that Auxilium continues to exist, Auxilium is sued herein in connection with Testim, Testopel, and Striant.

43. Defendant GlaxoSmith Kline LLC ("GSK") is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at the Philadelphia Navy Yard, 5 Crescent Drive, Philadelphia, Pennsylvania 19112. GSK is a wholly-owned subsidiary of GlaxoSmithKline plc, a British public limited company that is registered to do business in the United States.

44. As described in detail below, during relevant times, GSK was a co-promoter, with Auxilium, of Testim.

The Pfizer Defendants

45. Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, NY 10017.

46. Defendant Pharmacia & Upjohn Company Inc. ("Pharmacia") is a corporation existing under the laws of the State of Delaware with its principal place of business in New York, New York. In FDA filings, Pharmacia & Upjohn Company Inc. calls itself a division of Pfizer Inc.

47. Together, Pfizer, Inc. and Pharmacia are referred to in this Master Complaint as "Pfizer."

48. Pfizer is sued herein in connection with its TRT product Depo-Testosterone.

The Actavis Defendants

49. Defendant Actavis plc is an Irish corporation with its global headquarters in Dublin, Ireland. Actavis plc is the direct parent company of Defendant Actavis, Inc. and the indirect parent company of Defendants Actavis Laboratories UT, Inc., Watson

Laboratories Inc., Actavis Pharma Inc., and Anda Inc.

50. Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada with its principal place of business and its headquarters in New Jersey. Actavis, Inc. is the direct parent company of Defendants Actavis Laboratories UT, Inc., Watson Laboratories Inc., Actavis Pharma, Inc., and Anda, Inc. Actavis, Inc. was formerly known as Watson Pharmaceuticals, Inc.

51. Defendant Actavis Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business and its headquarters in New Jersey. Actavis Pharma Inc. was formerly known as Watson Pharma, Inc.

52. Defendant Actavis Laboratories UT, Inc. ("ALU") is a corporation organized and existing under the laws of the state of Delaware with its principal place of business and its headquarters in Utah. ALU was formerly known as TheraTech, Inc. and also as Watson Laboratories, Inc., a Delaware entity distinct from the Nevada entity sued herein as Defendant Watson Laboratories, Inc.

53. Defendant Watson Laboratories, Inc. is a corporation organized and existing under the laws of the state of Nevada with its principal place of business and its headquarters in New Jersey.

54. Defendant Anda, Inc. is a corporation organized and existing under the laws of the state of Florida with its principal place of business in New Jersey.

55. Together, Actavis plc, Actavis, Inc., Actavis Pharma Inc., ALU, Watson Laboratories, Inc., and Anda, Inc. are referred to in this Master Complaint as "Actavis."

56. Actavis is sued herein in connection with its TRT product Androderm.

FACTS COMMON TO ALL CLAIMS

The TRT Products

57. TRT products are exogenous (that is, originating outside the body) forms of the androgen testosterone. TRT products are available in several forms and delivery

methods, including gels and patches that deliver the drug transdermally, pellets that are inserted under the skin and deliver the drug subcutaneously, mucoadhesives designed to adhere to the gum and inner cheek, and intramuscular injections.

58. AndroGel, AbbVie's TRT product, is delivered transdermally and is applied to the skin in the form of a gel. It is available in either a 1% or 1.62% concentration. AndroGel was originally developed by Unimed in collaboration with Besins, S.A. Unimed sought FDA approval for AndroGel in 1999. Before the drug was approved by the FDA in 2000, Solvay Pharmaceuticals Inc. acquired Unimed Pharmaceuticals, Inc. and subsequently brought AndroGel to market. In 2010, Defendant Abbott Laboratories acquired Solvay's pharmaceutical division which included AndroGel. In 2013, Abbott Laboratories created AbbVie, a company composed of Abbott Laboratories' former proprietary pharmaceutical business, which included AndroGel.

59. At all relevant times, AbbVie was engaged in the business of, or was a successor-in-interest to entities that were engaged in the business of, researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling AndroGel for the use and application by men, including, but not limited to, Plaintiffs. At all relevant times AbbVie manufactured, sold, distributed and promoted AndroGel.

60. Axiron, Lilly's TRT product, is delivered transdermally in the form of a topical solution that is applied to the underarms. Lilly launched Axiron in the first quarter of 2011, after purchasing an exclusive license to commercialize the product from Australia-based Acrux. According to the terms of the license, Lilly agreed to pay $50 million upfront, an additional $87 million upon FDA approval of Axiron, and $195 million in potential post-approval milestones.

61. At all relevant times, Lilly was engaged in the business of, or was a

successor-in-interest to entities that were engaged in the business of, research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling Axiron for the use and application by men, including, but not limited to, Plaintiffs. At all relevant times Lilly manufactured, sold, distributed and promoted Axiron.

62. Fortesta, one of Endo's TRT products, is delivered transdermally and is applied to the skin in the form of a gel. It is available in a 2% concentration.

63. Fortesta was originally developed by Cellegy Pharmaceuticals, Inc., which sought FDA approval for the product in 2002. In November 2006, the New Drug Application for Fortesta was transferred to ProStrakan Pharmaceuticals, Inc. Before the drug was approved by the FDA in December 2010, Endo acquired the U.S. rights for Fortesta from ProStrakan Pharmaceuticals and subsequently brought Fortesta to market.

64. Delatestryl, another of Endo's TRT products, provides testosterone emanthate for intramuscular injections, and is available in 5 ml (200 mg/ml) dose vials.

65. At all relevant times, Endo was engaged in the business of, or was a successor-in-interest to entities that were engaged in the business of, research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling Fortesta and Delatestryl for the use and application by men, including, but not limited to, Plaintiffs. At all relevant times Endo manufactured, sold, distributed and promoted Fortesta and Delatstryl.

66. Testim, one of Auxilium's TRT products, provides a continuous 24-hour transdermal delivery system for testosterone following application by men to the skin of the chest and axillary (underarm) areas.

67. Testim is, and at all relevant times was, manufactured and produced for

or on behalf of and for the financial and economic benefit of Auxilium by DPT Laboratories, Ltd. ("DPT") in San Antonio, Texas. DPT is a contract development and manufacturing organization (CDMO) that specializes in fully-integrated drug manufacturing services. At all times material hereto, Auxilium was a seller, producer, marketer, promoter, co-promoter, and distributor of Testim, and utilized a nation-wide sales-force to detail, promote, co-promote, and market the Testim product to physicians, pharmacies, third-party benefits payers, health insurers, and healthcare providers

68. Testopel pellets, another of Auxilium's TRT products, are pellets that consist of crystalline testosterone and are implanted subcutaneously in men to achieve the slow release of testosterone for long-acting androgenic effect. Testopel was developed by Bartor Pharmacal Co. Inc. ("Bartor") during the early 1970s, and was approved by the FDA in 1972. In 2007, Slate Pharmaceuticals, Inc. ("Slate") and its founder by Robert Whitehead raised $5 million in an initial round of fundraising to purchase exclusive rights from Bartor to commercialize Testopel in the United States. In December of 2011, Actient Pharmaceuticals, LLC ("Actient") completed a transformative acquisition of Slate, and added Testopel to Actient's portfolio of products marketed to urologists. As of December 29, 2011, Slate Pharmaceuticals, Inc. operated as a subsidiary of Actient. In June of 2012, Actient acquired Bartor to secure the manufacturing capacity for the Testopel product, and reduce the cost of goods sold. On or about April of 2013, Auxilium completed the acquisition of Actient for $585 million in upfront cash plus certain contingent consideration and warrants to purchase Auxilium common stock.

69. Striant, another Auxilium TRT product, is a testosterone buccal system (relating to the mouth) mucoadhesive designed to adhere to the gum and inner cheek to provide a controlled and sustained release of testosterone through the buccal mucosa. Striant was developed by Columbia Laboratories, Inc. ("Columbia"), which sought FDA approval for the product in 2002. On or about April of 2011, Columbia entered into an

asset purchase agreement with Actient in which Columbia sold Striant to Actient for a combination of upfront cash and royalties on annual sales of Striant above a certain threshold. Columbia also licensed to Actient certain intellectual property related to the underlying progressive hydration technology for use in the treatment of hypogonadism and the treatment of low testosterone levels in men. Auxilium Pharmaceuticals Inc. purchased the rights to Striant in the United States in April of 2011. On or about April of 2013, Auxilium completed the acquisition of Actient. By that time, Auxilium's full complement of testosterone-containing prescription drug products included Testim, Striant, and Testopel.

70. At all relevant times, Auxilium was engaged in the business of, or was a successor-in-interest to entities that were engaged in the business of, research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling Testim, Testopel, and Striant for the use and application by men, including, but not limited to, Plaintiffs. At all relevant times Auxilium manufactured, sold, distributed and promoted Testim, Testopel, and Striant.

71. Depo-Testosterone is an intramuscular injection intended to be injected into the buttock muscle. The injection contains crystalline testosterone in an oil preparation.

72. At all relevant times, Pfizer was engaged in the business of, or was a successor-in-interest to entities that were engaged in the business of, research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling Depo-Testosterone for the use and application by men, including, but not limited to, Plaintiffs. At all relevant times Pfizer manufactured, sold, distributed and promoted Depo-Testosterone.

73. Androderm is a transdermal patch containing 2, 2.5, 4, or 5 mg of

testosterone, applied to the stomach, arm, back, or thigh. The drug enters the body through transdermal absorption.

74. The NDA for Androderm is, and has always been, held by Defendant ALU. ALU is also the manufacturer of Androderm.

75. At all relevant times, Actavis was engaged in the business of, or was a successor-in-interest to entities that were engaged in the business of, research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling Androderm for the use and application by men, including, but not limited to, Plaintiffs. At all relevant times Actavis manufactured, sold, distributed and promoted Androderm.

76. Each of the above TRT products delivers testosterone, a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

77. In men, serum testosterone levels normally begin a gradual decline after the age of thirty. Average testosterone levels for most men range from 300 to 1,000 ng/dl of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, other medications concomitantly administered, the method of measurement, and the laboratory in which the level is measured. As a result, many men who may have testosterone levels below 300 ng/dl on one day will have normal testosterone levels at other times. Additionally, testosterone levels gradually decline as men age. This decline in serum testosterone levels is a normal process that does not represent a medical condition or disease, and is a physiologic response to aging. It is not considered "classical hypogonadism."

78. Some men suffer from medical conditions that impair their ability to make

testosterone. These conditions include "primary hypogonadism" and "hypogonadotropic hypogonadism." "Hypogonadism" refers to diminished functional activity of the gonads, in men, the testes. "Hypogonadotropic hypogonadism" refers to hypogonadism due to impaired secretion of gonadotropins, a category of hormones secreted by the pituitary gland.

79. Hypogonadism is a specific and recognized condition of the endocrine system, which in men may involve the severely diminished production or nonproduction of testosterone. Primary hypogonadism occurs under circumstances of congenital or acquired pathologic insults to and conditions of the testes in men. Secondary hypogonadism, or hypogonadotropic hypogonadism, occurs when certain disorders cause suppression of gonadotropin-releasing hormone (GnRH), which in turns results in hypogonadism. Both primary and secondary hypogonadism are recognized pathologic endocrine disorders.

80. All of the above-described TRT products are approved as replacement therapy in connection with these disorders. None of the above-described TRT products has been approved to treat normal fluctuations or age-related declines in serum testosterone levels.

Regulatory History and Approved Uses

81. The FDA approved Delatestryl in or about 1953. Delatestryl is approved for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone, defined as:

> Primary hypogonadism (congenital or acquired) – Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy.
>
> Hypogonadotropic hypogonadism (congenital or acquired) – Idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary

importance.)

82. To date, the FDA has not approved Delatestryl for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

83. Testopel was approved by the FDA in or about 1972. As set forth on the label, Testopel is indicated

> for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.
>
> a. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy.
>
> b. Hypogonadotrophic hypogonadism (congenital or acquired) - idiopathic or gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

84. To date, the FDA has not approved Testopel for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

85. The FDA approved Depo-Testosterone on July 25, 1979, for testosterone "replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone" specifically primary hypogonadism and hypogonadotropic (or secondary) hypogonadism. Primary hypogonadism (congenital or acquired) is defined on the Depo-Testosterone label as "testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy." Hypogonadotropic hypogonadism (congenital or acquired) is defined on the Depo-Testosterone label as: "idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation."

86. To date, the FDA has not approved Depo-Testosterone for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

87. The FDA approved Androderm in 1995. As described on the label:

> ANDRODERM is an androgen indicated for replacement therapy in adult

> males for conditions associated with a deficiency or absence of endogenous testosterone.
>
> •Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter Syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
>
> •Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

88. To date, the FDA has not approved Androderm for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

89. The FDA approved AndroGel 1% on February 28, 2000. As described on the label:

> AndroGel 1% is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> • Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
>
> • Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations, but have gonadotropins in the normal or low range.

90. The FDA subsequently approved AndroGel 1.62% with the same indication as set forth for AndroGel 1%.

91. To date, the FDA has not approved AndroGel for any uses other than in

treating primary hypogonadism and hypogonadotropic hypogonadism.

92. The FDA approved Testim in or about October, 2002. As stated in the FDA's approval letter and on the Testim label, Testim is

> indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> • Primary hypogonadism (congenital or acquired) – testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol, heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH)) above the normal range.
>
> • Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

93. To date, the FDA has not approved Testim for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

94. The FDA approved Striant in or about June, 2003. As stated in the FDA's approval letter and on the Striant label, Striant is

> indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> • Primary hypogonadism (congenital or acquired) – testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol, heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH)) above the normal range.
>
> • Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

95. To date, the FDA has not approved Striant for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

96. The FDA approved Axiron on November 23, 2010. As approved by the FDA, Axiron is indicated "for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone"; these conditions are identified specifically as (a) primary hypogonadism (congenital or acquired) and (b) hypogonadotropic hypogonadism (congenital or acquired). The Axiron label defines these conditions as follows:

> Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
>
> Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

97. To date, the FDA has not approved Axiron for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

98. The FDA approved Fortesta on or around December 29, 2010. The Fortesta label states that Fortesta is

> indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> • Primary hypogonadism (congenital or acquired) – testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol, heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH)) above the normal range.
>
> • Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic

> gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

99. To date, the FDA has not approved Fortesta for any uses other than in treating primary hypogonadism and hypogonadotropic hypogonadism.

100. To date, the FDA has not approved any TRT product for any uses other than in treating primary and hypogonadotropic hypogonadism.

101. Nonetheless, as described in more detail below, beginning approximately in 1999, Defendants began marketing their TRT products for off-label use, for an invented condition called "Low T." At the same time, Defendants failed to provide adequate warnings of the dangerous effects of these products, so that prescribers and consumers were misinformed about both the risks and the benefits of TRTs.

Defendants' Marketing to Consumers and Physicians for Off-Label Use

102. A manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an "off-label" purpose.

103. A manufacturer misbrands a drug if the labelling, or any of the manufacturer's promotional and advertising materials, describe an intended use for the drug that has not been approved by the FDA.

104. Promotional materials are misleading if they suggest that a drug is useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience.

105. Promotional materials are misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence or substantial clinical experience.

106. Promotional materials are misleading if they fail to reveal facts that are material in light of the representations made, or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials.

107. The FDA did not, and never has, approved any TRT product for the treatment of:

a. age-related declines in testosterone levels in men;
b. age-related symptoms;
c. mood disorders, including depression or "grumpiness" or inability to concentrate;
d. lack of sexual interest or decreased libido;
e. disorders of erectile function or erectile dysfunction;
f. loss of muscle mass; or,
g. bone strength or density abnormalities.

108. Nonetheless, Defendants marketed their TRT products to doctors and directly to consumers for these symptoms, without reference to the clinical conditions for which these drugs were approved.

109. As described in detail below, all of the Defendants expanded the indications for use of testosterone replacement therapy products by promoting and detailing "Low T" as an acquired form of hypogonadism.

110. Defendants took advantage of an intentional ambiguity in TRT product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

111. Defendants intentionally, knowingly, and deceptively misrepresented the clinical indications for testosterone replacement therapy, and sought to conflate "classical hypogonadism" with a pharmaceutical industry condition denominated "Low T."

112. This ambiguity was additionally used by Defendants to promote label expansion and "off-label" use of testosterone through the recruitment of "thought leaders," "key opinion leaders," and sponsored and funded researchers and research in testosterone replacement therapy.

113. At all times herein mentioned, the officers and directors of each of the Defendants participated in, authorized, and directed the production and promotion of their respective TRT products when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said products and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiffs herein.

AbbVie's Off-Label Marketing

114. At all times material hereto, and since the time that AndroGel first received approval from the FDA, AbbVie knew and understood the FDA-approved indications for clinical use of the AndroGel products. AbbVie expanded the indications for use by promoting and detailing "Low T" as an acquired form of hypogonadism, and made use of a perceived intentional ambiguity in the AndroGel product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

115. In 2000, when reviewing the drug's advertisements, the FDA told AndroGel's maker that "claims and representation that suggest that AndroGel is indicated for men with 'age-associated' hypogonadism or 'andropause' are misleading." The drug, the FDA said, was only approved for men with hypogonadism. Despite this admonition from the FDA, AbbVie continued to market and promote testosterone replacement therapy for "andropause" and "Low T."

116. AbbVie intended to promote AndroGel for off-label use from the very beginning. In 1999, when Unimed asked for FDA approval of AndroGel, it asserted that hypogonadism was estimated to affect approximately "one million American men." Defendants represented to the FDA that they would market and sell the drug to this patient population of one million men who have an actual diagnosis of hypogonadism with an associated medical condition. This was a false representation that it made to the FDA in order to obtain approval of the drug.

117. In 2000, when the FDA approved AndroGel, the company announced that the market had increased from one million men to "four to five million American men." By 2003, the number again increased to "up to 20 million men." These numbers did not, and could not represent, the number of men with the conditions for which AndroGel is indicated, which are believed to be substantially smaller.

118. Indeed, a study published in the *Journal of the American Medical Association* ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001–2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription. A Canadian study showed that only about 6.3% of men who were prescribed testosterone actually met the diagnostic criteria for hypogonadism.

119. These sales to men with no evidence of hypogonadism were the result of a coordinated massive advertising campaign targeted toward men who did not have hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. AbbVie's direct-to-consumer marketing efforts were designed to convince men that they suffered from a non-existent and unrecognized medical condition called "Low T," which was a term for low testosterone. AbbVie orchestrated a national disease awareness media blitz that purported to educate male consumers about the signs of low testosterone. The marketing campaigns consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential TRT product users, and online media including unbranded websites, such as IsItLowT.com, DriveForFive.com, and GetTestedForLowT.com.

120. The television advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any

of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness-all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

121. AbbVie's national education campaigns included the creation and continued operation of the websites IsItLowT.com, DriveForFive.com and GetTestedForLowT.com. The websites assert that millions of otherwise healthy men experience low testosterone and encourage male visitors to "Take the 'Is it Low T' Quiz." The "Is it Low T" quiz asks men if they have experienced potential signs of low testosterone, including "Have you experienced a recent deterioration in your ability to play sports?," "Are you falling asleep after dinner?," "Are you sad and/or grumpy?," and "Do you have a lack of energy?"

122. AbbVie's physician detailing sales forces directed physicians to access these websites to better educate themselves and patients on "Low T" and TRT products.

123. Dr. John Morley, director of endocrinology and geriatrics at the St. Louis University School of Medicine, developed this quiz at the behest of Dutch pharmaceutical company Organon BioSciences, in exchange for a $40,000 grant to his university. The pharmaceutical company instructed Dr. Morley, "Don't make it too long and make it somewhat sexy." Dr. Morley drafted the questionnaire in 20 minutes in the bathroom, scribbling the questions on toilet paper and giving them to his secretary the next day to type up. Dr. Morley admits that he has "no trouble calling it a crappy questionnaire" and that it is "not ideal." This is the "Low T Quiz" used on the IsItLowT.com website. *See* Natasha Singer, "Selling that New-Man Feeling," *New York Times,* Nov. 23, 2013. It is also referred to as the "**A**ndrogen **D**eficiency in **A**ging **M**en," or ADAM, questionnaire.

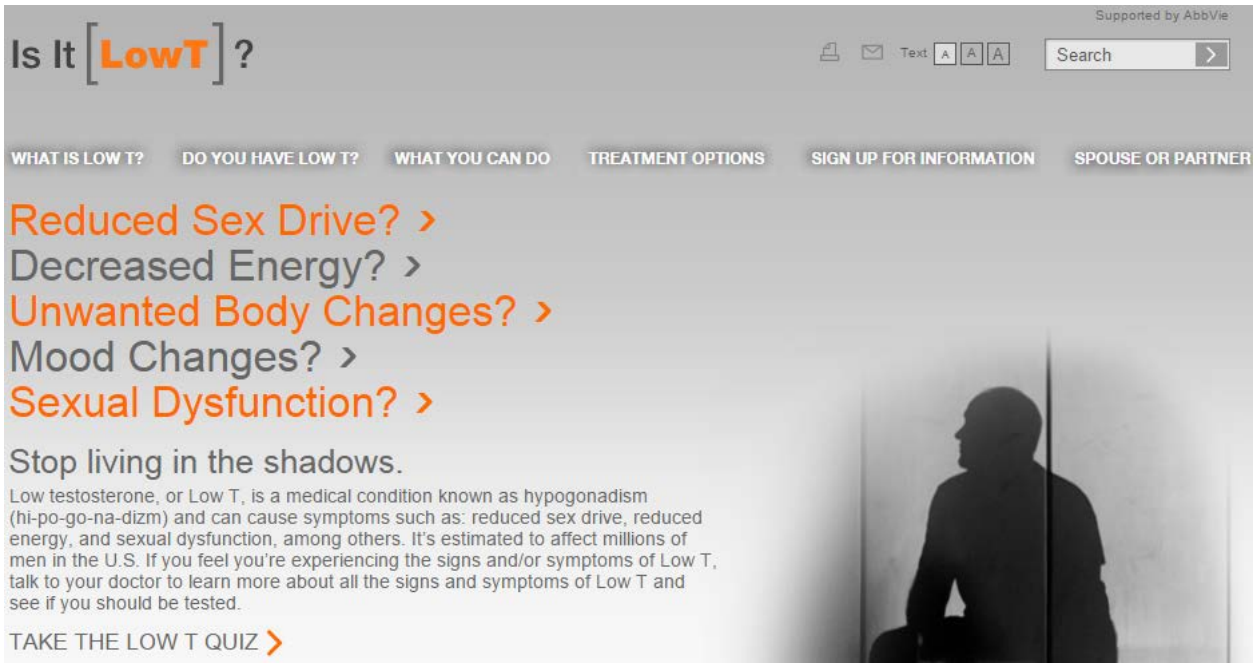
124. Since the FDA approved TRT products for a very specific medical condition called hypogonadism, AbbVie also sought to convince primary care physicians that hypogonadism is synonymous with "Low T" and that low testosterone

levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

125. AbbVie convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

126. AbbVie manufactured, sold and promoted these drugs to treat a non-existent medical condition that it called "Low T," which was a name they created for the constellation of symptoms experienced by men as a result of the normal aging process. Defendants marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

127. AbbVie's marketing actively blurs the line between AndroGel's approved indications and "low testosterone." For example, a website sponsored by AbbVie,



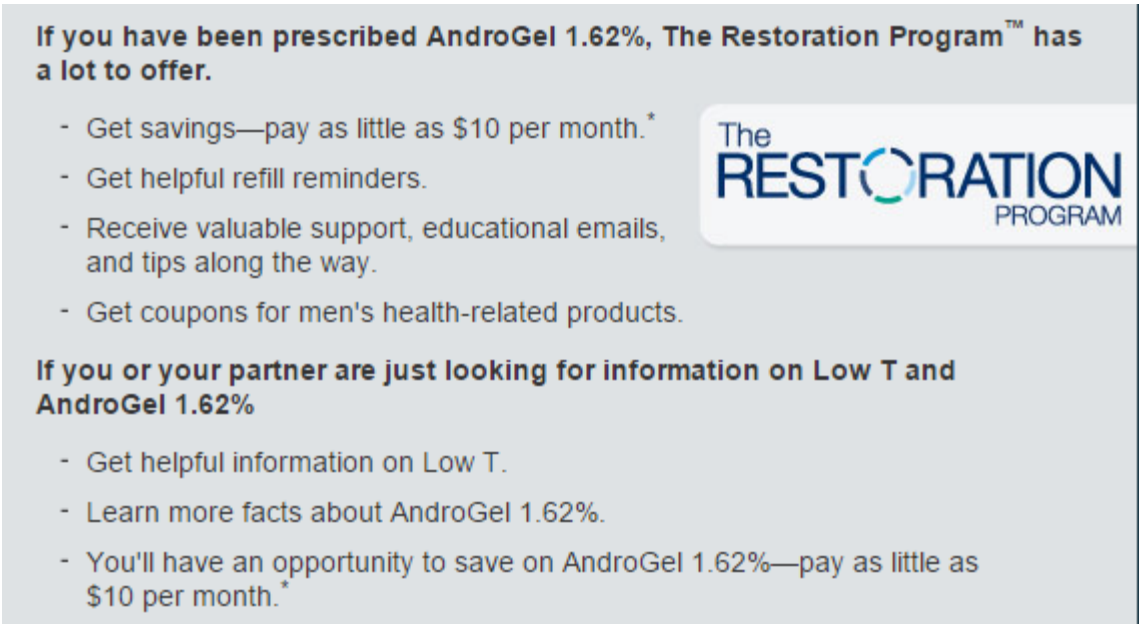
http://www.isitlowt.com, instructed men to ask their doctors about AndroGel if their testosterone was low:

128. A 2004 memo on AndroGel sales strategies said the sales force was putting extra emphasis on rural areas, since "rural doctors are typically very accessible, give us plenty of time to teach them the right way to diagnose and treat, and they have the patients."

129. AbbVie successfully created a robust and previously nonexistent market for their drugs. AbbVie spent $80 million promoting AndroGel in 2012. The company also spent millions on unbranded marketing including commercials and websites, including IsItLowT.com and DriveForFive.com, sites which recommend that men have regular checkups with their physicians and five regular tests done: including cholesterol, blood pressure, blood sugar, prostate-specific antigen, and testosterone.

130. AbbVie's advertising paid off in a return of $1.4 billion in sales during the past year (2013), making AndroGel the biggest selling androgen drug in the United States. Sales of replacement therapies have more than doubled since 2006, and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, "Are Testosterone Drugs the Next Viagra?," *Bloomberg Businessweek,* May 10, 2012.

131. In order to ensure physicians were more likely to prescribe and consumers were more likely to purchase TRT products, AbbVie offered financial assistance in obtaining TRT prescriptions. One example, AndroGel's "Restoration Program," as shown on AbbVie's website (http://www.androgel.com/savings-and-resources) offers AndroGel 1.62% for "as little as



$10 per month."

132. In early 2013, Medical Marketing & Media named two AbbVie executives as "the all-star large pharma marketing team of the year" for promotions of AndroGel and unbranded efforts to advance Low T.

133. AbbVie engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T."

134. The marketing program sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that the use of TRT is safe for human use as a treatment for "Low T," even though AbbVie knew these to be false, and even though AbbVie had no reasonable grounds to believe them to be true.

135. At all times material hereto, AbbVie's marketing strategy included the use of sales or drug detailing representatives ("reps") and marketing and brand team personnel who performed on-line and in-person TRT product detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

136. AbbVie's drug detailing reps provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the TRT products, as well as discount and/or rebate coupons to give to patients for the purchase of TRT products.

137. AbbVie's drug reps detailed and marketed TRT products to physicians as approved and indicated for the treatment of age-related declines in testosterone levels

and age-related symptoms.

138. AbbVie denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

139. AbbVie knew and understood the meaning of the terms "off-label" and "label expansion."

140. AbbVie knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

141. AbbVie marketed, promoted, and detailed TRT products for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, promoting the idea that "Low T" was an indication for clinical use of TRT products.

Lilly's Off-Label Marketing

142. Lilly engaged in a similar off-label marketing campaign for its TRT, Axiron.

143. Lilly began marketing Axiron in the United States in 2011. The product was originaly developed by Acrux, which still owns the intellectual property rights to Axiron. Acrux executed and funded the entire development of Axiron, through to approval by the FDA. Thus, it was responsible for completing the necessary clinical trials for Axiron in order to gain regulatory approval from the FDA.

144. In March of 2010, Acrux and Eli Lilly and Company entered into an exclusive worldwide license agreement for the commercialization of Axiron. The agreement was the single largest product licensing deal in the history of Australian biotechnology. The licensing agreement permitted Lilly to launch Axiron in the United States with potential distribution into another 142 countries.

145. Lilly has agreed to pay Acrux royalties for Axiron sales based on milestones agreed to in the license agreement. Specifically, according to the terms of the license, Lilly agreed to pay $50 million upfront, an additional $87 million upon FDA approval of Axiron, and $195 million in potential post-approval milestones

146. Lilly's press release announcing the deal made it clear that Lilly intended to promote Axiron for off-label and label expanding uses. In the "About Hypogonadism" section, Defendant Lilly explained: "Testosterone deficiency in men (hypogonadism) is associated with a number of clinical problems. It has been estimated that up to 39% of men over 45 years of age may have testosterone levels below the normal healthy range [citing the Mulligan HIM Study]. However, in the majority of men this remains undiagnosed, with approximately 10% of those with the condition receiving treatment." Even before Axiron's approval, Lilly sought to link age-appropriate testosterone levels to other co-morbidities and to suggest testosterone treatment was appropriate for nearly half of the male population over the age of 45.

147. Lilly expanded the indications for use by promoting and detailing "Low T" as an acquired form of hypogonadism, and advantaged intentional ambiguity in the Axiron product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

148. On its Axiron.com website, Lilly states: "Indication: AXIRON is used to treat adult males who have low or no testosterone."

149. Lilly has poured significant monies into its Axiron commercialization efforts. Lilly spent almost $122 million on Axiron promotion in 2013, spread among the peer selling, publication, and direct to consumer enterprises.

150. The consensus among both observers (such as the biopharmaceutical research company Encuity Research) and participants (such as Acrux, the company from whom Lilly purchased the license to market Axiron) is that "[t]he ramp-up of promotional activity is clearly having its desired effect." Fueled by Lilly's success

promoting Axiron, Acrux's stock soared 63% in one month alone in July 2014.

151. When Lilly entered the TRT market in Q1 2011 with Axiron, the testosterone market was already nearing $2 billion total in annual sales. In other words, Lilly entered a mature market. This did not stop Lilly from adopting the philosophy of "making a bigger pie" by vigorously promoting the disease state and alleged off-label comorbidities Axiron was supposedly safe and effective in treating.

152. Lilly promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Lilly overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

153. Lilly has hosted numerous events where doctors who had been trained and/or approved by Lilly would falsely oversell the efficacy and safety of Axiron and provide favorable information on the off-label use of Axiron, often under conditions where physicians were compensated for attending the presentation. Lilly has funded (and continues to fund) scores of such events.

154. Lilly created and controlled a large enterprise composed of medical marketing firms and dozens of physicians who routinely promoted Axiron to other physicians in venues all across the country. Lilly maintained sufficient control over this enterprise to select and approve the content of the programs and the physician participants that would deliver the off-label messages. Physicians who were not receptive to promoting Axiron for the off-label uses were not considered for inclusion in the enterprise. The physicians (mostly primary care physicians) who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Lilly.

155. Lilly promoted Axiron for off-label and label expanding uses through

these physician speakers. Lilly has paid extravagant sums of money to leading urologists and endocrinologists in exchange for their publicized support of Axiron. For example, Dr. Irwin Goldstein, President and Director of the San Diego-based Institute for Sexual Medicine and a Lilly physician participant, has been paid at least $122,000 by Defendant Lilly in the past three years for travel, speaking, meals, and consulting. Dr. L. Dean Knoll, of Urology Associates Nashville, has been paid over $200,000 by Lilly in the past several years for consulting, speaking, meals, travel, and "other." Dr. Culley C. Carson III, who is the Rhodes Distinguished Professor of Urology at UNC-Chapel Hill has been paid a comparatively modest $55,000 by Lilly for travel, consulting, meals, speaking, and "other" since 2009.

156. For all of the money that has been disclosed, many of Lilly's payments remain under the radar. Lilly funnels millions of dollars per year toward so-called "educational programs" in the form of continuing medical education (CME) events. The events are remarkably homogenous both in content and in terms of the chosen faculty/speakers for such events. This is because these are pre-packaged programs prepared and paid for by Lilly, which then passes them off in the form of educational "grants" to disguise Lilly's role and payments to the physician lecturers.

157. Lilly's Grant Office, for example, states that it "provides grants and charitable contributions for healthcare profession education ... programs in a variety of therapeutic areas." Those therapeutic areas more than often coincide with the products Lilly is promoting. Lilly only cagily acknowledges that "it is possible that the educational programs funded by the company through grants have discussed off-label uses of our products."

158. According to the 2013 Lilly Grant registry, Defendant Lilly expended approximately $2.75 million on so-called "Educational Programs" falling under the disease state "Urology – Hypogonadism" during the 2013 calendar year. This followed similar expenditures of approximately $2.3 million in 2012. Lilly expended tens of

millions more on educational programs for supposed co-morbid diseases, such as erectile dysfunction, Alzheimer's, diabetes, etc., where off-label references to TRT or Axiron treatment might "possibly" have been discussed. The funding for these programs (and for the physician participants) was channeled through dozens of Lilly's vendor participants.

159. Lilly employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Axiron for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Axiron for both approved indications and for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Axiron; (d) wrongfully and illegally compensating physicians for causing the prescribing of Axiron; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Axiron for both on-label and off-label uses, and then disseminating copies of such studies by the thousands; (f) intentionally misrepresenting and concealing Lilly's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Axiron to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Lilly and other participants in these ventures.

160. For example, AccelMed, LLC is the first-listed vendor on Lilly's 2013 Grant Registry, having received nearly $450,000 for three hypogonadism-related programs in 2013. As cryptically conceded on AccelMed's website, the focus of such programs was not purely educational: "We understand the sensitive balance between science, adult learning, and tactical preferences that can turn educational challenges into opportunities." Of course, the "tactical preferences" and "opportunities" related to the commercialization efforts by AccelMed's pharmaceutical clients for their products,

which included Lilly for its Axiron product.

161. Unsurprisingly, the faculty presenting these AccelMed programs includes physician participants in Lilly's peer selling enterprise who presented at these and a multitude of other Lilly-sponsored "educational programs." For example, in a 2014 AccelMed Program titled "Practical Primary Care Strategies for Diagnosing and Managing Hypogonadism in Men – Best Practices to Improve Patient Outcomes," the two faculty lecturers were Dr. Martin Miner and Dr. Matt T. Rosenberg, both of whom are Axiron physician participants and are frequently on the roster of Lilly lecturers at such events. Dr. Rosenberg disclosed serving as a consultant for Lilly (among other pharmaceutical companies). Dr. Miner disclosed such arrangements with AbbVie and Endo, but not for Lilly, which is surprising since Dr. Miner has disclosed elsewhere that he served on Lilly's advisory board.

162. Lilly expected that Dr. Miner and Dr. Rosenberg would present on the off-label uses of TRT drugs, including Axiron. Indeed, the "Program Overview" of this CME-accredited program states: "Testosterone deficiency is associated with a well-documented increase in risk of mortality and detrimental effects on quality of life: loss of energy and libido, erectile dysfunction (ED), joint pain and stiffness, memory impairment, irritability, and depression. In spite of this, hypogonadism remains an under diagnosed syndrome that, with its links to age, obesity, type 2 diabetes mellitus (T2DM), and metabolic syndromes, is becoming increasingly relevant."

163. Assuming that Dr. Miner and Dr. Rosenberg followed the "Program Overview" (as well as the script and slides prepared by Lilly and provided through AccelMed), it appears that the entire program centered on the off-label or label expanding uses of Axiron and TRT drugs. Furthermore, because the payments to Dr. Miner and Dr. Rosenberg were funneled by Lilly through AccelMed, they are not listed in the physician payment databases that are publicly available. For example, publicly available reports show Dr. Miner having only received a few thousand dollars in total

from Lilly despite his participation in dozens of these CME lectures.

164. Similarly, Paradigm Medical Communications, LLC released in November 2013 a "Controversies in the Treatment of Male Hypogonadism" CME program "supported by an educational grant from Lilly". The faculty included two prominent Lilly physician participants, Drs. Culley C. Carson and Mohit Khera. Dr. Carson is the Chief of Urology at UNC-Chapel Hill, but also serves on Lilly's advisory board and speaker's bureau. Dr. Carson has received hundreds of thousands of dollars in payments from pharmaceutical companies, including Lilly. Dr. Khera is a Urology professor at Baylor, and is likewise on Lilly's speakers bureau and has been paid at least $75,000 by Defendant Lilly in the last three years alone. Exemplifying how Lilly prepackaged the scripts and slides for these events, the "Statement of Need" for this CME reads almost identically to the "Program Overview" in the previous CME discussed and presented by Dr. Miner and Dr. Rosenberg: "The condition is associated with symptoms including erectile dysfunction, loss of libido, and decreased energy levels, as well as comorbidities including obesity, decreased muscle mass, and potential cardiovascular complications, and can result in decreased vitality and a reduced quality of life. However, studies have shown that a significant proportion of men with hypogonadism go undiagnosed, or do not receive testosterone replacement therapy due to either poor physician understanding of the benefits and safety of therapy or physicians' concerns of exacerbating other comorbid conditions."

165. The consistency of the message in all the Lilly-supported CME events is attributable to the fact that Lilly controlled the content of these packages as part of its broader marketing efforts.

166. In another example, Lilly made two payments of $68,138 to vendor participant Med-IQ, LLC, for two runs of the program "Tackling Taboos: Optimizing Management of Men's Health Through Evidence-Based Care and Effective Patient Communication." The Faculty for each event were comprised of Dr. Rosenberg, who

again disclosed extensive pharmaceutical ties, including to Lilly, and Dr. Steven A. Kaplan, who disclosed no potential conflicts. However, a review of ProPublica's DocDollars database reveals that Dr. Kaplan received hundreds of thousands of dollars from pharmaceutical companies, much of it through his consulting firm Solera Consulting, LLC. The slides for the Med-IQ CME, which are available online, begin their discussion of hypogonadism (after a discussion of erectile dysfunction) with the assertion that "Hypogonadism Is Underdiagnosed and Undertreated," relying on the Mulligan HIM Study funded and created by AbbVie. The very next slide launches into off-label treatment suggestions; titled "Common Comorbidities of Hypogonadism," the slide listed comorbidities (along with odds ratios) such as obesity, diabetes, hypertension, hyperlipidemia, osteoporosis, and Asthma/COPD. The next slides focus on "Screening for Low Testosterone" and reproduce the ADAM questionnaire developed by AbbVie as well as list the vague set of symptoms found on the www.Axiron.com website, including: fatigue; poor concentration; sleep disturbance; decreased muscle mass; decreased erections; and fragility fractures.

167. Dr. Louis Kuritzky, a Family Medicine Professor at University of Florida, declared in a Lilly-sponsored video that "replacement of testosterone is a very satisfying process." Lilly paid almost $80,000 toward Dr. Kuritzky's seven-minute video lecture delivered to the 2013 Men's Health World Congress, available on the Foundation for Men's Health website. Neither the website nor the video discloses Lilly's involvement. Dr. Kuritzky himself has received tens of thousands of dollars from Lilly and other pharmaceutical interests for consulting, speaking, and other services. In a four-minute lecture at the same Men's Health World Congress by Axiron physician participant Dr. Jed Kaminetsky, who is on the faculty at NYU Medical School, Dr. Kaminetsky attempted to address the association of TRT with prostate cancer growth by stating his opinion that TRT has "very little effect on the prostate." Neither the website nor the video discloses Lilly's involvement. Dr. Kaminetsky has been paid

nearly $400,000 by Lilly alone since 2009 for research, consulting, speaking, travel, and meals.

168. At an American Association of Family Practitioners (AAFP) conference held in September 2013 in San Diego, Lilly (along with AbbVie) gave $150,000 for the AAFP IDEAL "Hitting Below the Belt: Winning Strategies to Promote Men's Health" presentation. The series of panels depicted muscular and shirtless prizefighters and were boxing-themed. Several of the panels were TRT-related with titles such as "Go Toe to Toe with Testosterone Deficiency" and "Don't Get Caught Against the Ropes – Confirm the Diagnosis." In conjunction with the "Go Toe to Toe" panel, a "Clinical Pearl" of wisdom offered was to "[e]xplore the possibility of testosterone deficiency in certain middle-aged and older patients, such as those with type 2 diabetes and symptoms such as low libido and erectile dysfunction." The identity of the presenter(s) for these TRT panel slides is unclear, but the message was classic off-label, andropausal promotion by Lilly.

169. These CME-driven efforts were complemented with traditional detailing by Lilly's sales force. Lilly's sales force had been promoting Lilly's erectile dysfunction drug, Cialis, since 2003, and thus was well positioned to take on Axiron as well, given "Lilly's success with Cialis and the synergy between prescribing groups of Axiron and Cialis ...." The sales force also arranged for the utilization of non-CME physician lecturers to whom Lilly's sales and marketing teams served as handlers. Lilly's sales force arranged less formal lectures and roundtables, publicized them to primary care physicians on details, drove the lecturers to the events, and provided them with scripts and slides for the events. As with the CME events, the lectures contained largely uniform messaging centering on: (1) the off-label uses for Axiron; (2) suggesting utilization of vague screening criteria such as the ADAM questionnaire or the list of symptoms on Axiron's website; and (3) disease fear mongering by suggesting that as little as 5% of men with "low T" were being treated. Eventually, physician speakers

were also asked to make reassuring statements concerning cardiovascular safety of TRT and of Axiron.

170. Lilly also sought to create the impression that the medical literature supported TRT and Axiron for off-label and label expanding uses.

171. As noted by Acrux, Lilly had undertaken clinical trials focusing largely on off-label usage of Axiron, "represent[ing] significant commitments by Lilly to expanding the therapeutic indications for Axiron." Notably, Lilly has yet to request the FDA to expand the FDA-approved indications for Axiron. Whether the indications were FDA-approved mattered little to Lilly, so long as Axiron was being prescribed for these expanded indications.

172. Clinical trials undertaken by Lilly to support the "expanded" off-label use of Axiron included: "A trial for enhanced sex drive and energy levels"; "An ejaculatory dysfunction trial"; and "A trial for suboptimal responders to testosterone gels other than Axiron." Acrux was hopeful that other off-label pursuits would materialize, stating "[t]here is scope for testosterone use in other indications such as cachexia, which is the muscle wasting and weight loss that occurs in the later stages of cancer." Acrux also stated that "[e]xploratory clinical studies have been publicized investigating testosterone effects in Alzheimer's and Multiple Sclerosis. Another slide also listed chronic opioid use, renal disease, Type II Diabetes, and obesity as potentially ripe markets for testosterone.

173. Notably, all three of the studies referenced above have been completed, but no trial results have been published and no publications have been released. In fact, the entries for all three trials on clinicaltrials.gov list Lilly alone as the "Study Sponsor," "Responsible Party," and "Investigator." No research physicians or collaborators are named. This is because Lilly is in control of all aspects of these studies, from inception and protocol creation to resulting publications.

174. Nevertheless, the efficacy study titled "A Study in Men with Low

Testosterone to Measure the Effects of Testosterone Solution on Testosterone Levels, Sex Drive and Energy" bears the clinical trials identifying number NCT01816295, which is listed on the Urologic Consultants of Southeastern Pennsylvania's website under clinical trials being conducted by that physician group. A sampling of the group's physicians reveals extensive pharmaceutical ties, with several physicians raking in hundreds of thousands of dollars from Lilly and other pharmaceutical interests. For example, Dr. Phillip Ginsberg, seated front and center in the physician practice's team photo, has received nearly $250,000 in payments from Lilly and others since 2009 for meals, speaking, travel, consulting, and "combination." His colleague Dr. Richard Harkaway has been paid at least $365,000 by Lilly and others for speaking, travel, consulting, and meals since 2009. Dr. Laurence Belkoff has received over $200,000 from Lilly and other pharmaceutical interests for research and speaking since 2009. Once the (doubtless) favorable study results for this study are published, the study investigators and potential authors will be tapped by Lilly to ride the speaker circuit, proclaiming the study's positive results supporting Axiron's off-label use in exchange for handsome speaker payment fees. As is clear from the trial's clinicaltrials.gov entry, the trial is a Lilly-funded marketing venture designed, as stated by Acrux, for the purpose of "expanding the therapeutic indications for Axiron."

175. Even the studies supporting Lilly's NDA approval for Axiron followed the usual steps and involved the usual physician participants. For example, Lilly's www.Axironmd.com website (for healthcare professionals) states under the "Clinical Study" tab that "AXIRON was evaluated in a multicenter, open-label, 120-day trial of 155 men with hypogonadism." Lilly then relates some of the positive findings of the open-label study for potential prescribing physicians to cogitate on, while failing to disclose Lilly's and Acrux's extensive involvement in the study, including the resulting publication, Wang *et al.*, *Efficacy and safety of the 2% formulation of testosterone topical solution applied to the axillae in androgen-deficient men*, J. CLIN. ENDOCRINOLOGY (2011)

75:836-4. Dr. Christina Wang, whom Lilly recruited from AbbVie's Peer Selling and Publication Enterprises, served as the lead author on the study. However, Dr. Wang's exact role in the study is unclear, as the study's clinicaltrials.gov entry lists the "Study Sponsor" as "Eli Lilly and Company," the "Responsible Party" as "Chief Medical Officer, Eli Lilly," the "Investigators" as "Eli Lilly and Company," and "Collaborators" as "None Provided." Two of Dr. Wang's co-authors were Acrux employees, and all of the authors (including Dr. Wang) with the exception of Dr. Niloufar Ilani, disclosed financial ties to Lilly, Acrux, or both. Dr. Wang herself disclosed a consulting relationship with Lilly and having received research grants from Acrux.

176. The "authors" went on to acknowledge several Lilly employees and employees of a ghostwriter company called "i3 Statprobe" for their purported "critical review of the manuscript." The company i3 Statprobe's website (www.i3global.com) redirects to inVentiv Health clinical (http://www.inventivhealthclinical.com/). Among the services provided by i3 Statprobe is "Phase IIB-III Clinical Trial Medical Writing." Lilly's study was a Phase III clinical trial. Described as providing a "full complement of medical writing services" through at least "160 writers, editors, and writing management staff[,]" the medical writers "provide all your documentation and writing needs." One of the medical writers "acknowledged" by Dr. Wang is Rich Pistolese, who holds a bachelor's degree in chemistry. This study was used to support Axiron's NDA and is featured prominently on Lilly's website and in the prescribing information.

177. Study "authors" such as Dr. Wang exercised little control over the study's protocol and only had a superficial role in the dissemination of the study results and the creation of the medical literature pieces. Nevertheless, Dr. Wang's professional reputation was enhanced as the "lead author" of the study. Dr. Wang boasts on her faculty profile at UCLA School of Medicine's website that she "has authored over 250 peer-reviewed publications. . . ." Dr. Wang was paid more than $250,000 in 2011 and 2012 by Lilly for her "research."

178. Lilly created study protocols consistent with Lilly's intended Axiron marketing messages, funded these studies to completion, exercised total control over the decision to publish and the format and substance of the resulting medical journal articles, and paid largely through its vendor participants prominent physicians to lend their names for "authorship" of such articles in exchange for handsome payments. Defendant Lilly then masqueraded these predetermined study results, often ghostwritten by Lilly and its vendor participants, as credible science on its websites, through reprints distributed by Lilly's sales force to physicians, and through physician speakers.

179. With the help of its vendor associates, Lilly has engaged in direct to consumer ("DTC") advertising campaigns that fraudulently, misleadingly, and unlawfully concealed and minimized serious health risks associated with the use of Axiron, and promoted Axiron as safe and effective for unapproved off-label uses lacking scientific support.

180. Lilly, along with other Defendants, coordinated massive advertising campaigns targeted toward men who do not have hypogonadism, nor have low or no testosterone in conjunction with associated medical conditions. The direct to consumer marketing is designed to convince men that they suffered from a non-existent and unrecognized medical condition called "Low T", a term for low testosterone. Lilly, along with other Defendants, orchestrated national disease awareness media blitzes that purport to educate male consumers about the signs of low testosterone. The marketing campaigns consist of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Axiron users, and online media.

181. The advertisements disseminated by Lilly suggested that various symptoms often associated with other conditions may be caused by low testosterone and encouraged men to discuss testosterone replacement therapy with their doctors if

they experienced any of the "symptoms" of low testosterone. These "symptoms" included "decreased sexual desire (libido)," "erectile dysfunction," "fatigue and loss of energy," "depressed mood," "loss of body hair (decreased need to shave)," "decrease in strength," and "osteoporosis (decreased bone density)." All of these are general symptoms that are often a result of aging, weight gain, or lifestyle, rather than conditions associated with hypogonadism.

182. Targeted DTC advertising of Axiron was designed to drive patients to ask their physicians for prescriptions of Axiron. Both branded Axiron and unbranded DTC disease state marketing were thus undertaken by Lilly and its associates, and were geared specifically toward expanding the definition of hypogonadism or branding "Low T" as a recognized disease state in need of treatment, preferably with Axiron.

183. While running their disease awareness campaigns, Defendants promote Axiron as an easy to use topical testosterone replacement therapy. For example, Lilly promotes Axiron as the "only underarm low testosterone treatment." Lilly contrasts its product's at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

184. Lilly invested heavily in DTC advertising. Of the $122 million Lilly spent on promoting Axiron in 2013, nearly 70% of it ($84 million) funded DTC efforts. Lilly spent more than double the amount of money on Axiron DTC alone in 2013 than the combined total for all promotional efforts of TRT manufacturers for Testim, Testopel, Fortesta, and Androderm. As stated by Encuity Research, "[m]anufacturers have taken note of how successful DTC advertising has been for driving market share in other lifestyle markets, such as erectile dysfunction, dermatology, and eye care." For its part, having the experience of promoting Cialis for approximately a decade, Lilly understood the importance of wildly extravagant DTC spending efforts in commercializing Axiron.

185. Lilly associated with high-profile (and high budget) New York advertising firms to develop a multitude of Axiron commercials, most variations on the same

themes of lean and attractive middle-aged men with grey hair applying Axiron and then power boating or sporting (or otherwise exuding masculinity) while their young attractive female partners look upon them lustfully.

186. In addition to the "Vacation" commercial produced by Grey Group, these DTC ads, which are highly suggestive of off-label use and which rarely mention hypogonadism, have won national recognition.

187. For example, Grey New York produced a television ad titled "A New Day" in the Summer of 2013, which won the bronze medal at the 2013 DTC National Advertising Awards. The television ad does not mentions "hypogonadism" a single time and shows a fit middle-aged man waking up in the morning with a burst of energy, applying Axiron in the bathroom, suiting up and flirting with his attractive wife over breakfast, and then striding confidently into the office as the commercial cuts to Axiron's classical silhouette of a chiseled man applying Axiron to his raised underarms. As observed by Deborah Dick-Rath of Medical Marketing & Media (MM&M), the image is evocative of "a classic Greek statue of a very athletic man who probably never heard of 'low T.'"

188. The "A New Day" commercial was designed to suggest to men that they could use Axiron to treat low energy levels, which is consistent with the off-label messages being developed as part of the Lilly's broader marketing enterprise. Lilly's www.axiron.com website lists "[f]atigue and loss of energy" as one of several "[s]igns and symptoms of low testosterone (Low T)." The FDA has not approved Axiron to treat "[f]atigue and loss of energy," nor has Axiron been proven to be safe or effective at treating "fatigue," which for many men is likely attributable to something other than the rare condition of hypogonadism.

189. Another Axiron television commercial featured our patient and protagonist serving as a lively home plate umpire in a baseball game. As he slaps on his face mask, he extols the listener: "My mantra? Trust your instincts to make the call."

The commercial then cuts to our umpire applying Axiron in the bathroom, giving himself a reassuring look in the mirror before leaving the bathroom, and proceeding energetically to call a runner out at home plate. Hypogonadism is again never mentioned and the commercial urges patients to self- diagnose based on "instincts" and then ask their physicians for treatment. Lilly manipulated those instincts by suggesting that low testosterone was the root cause of any number of medical conditions and generalized symptoms.

190. Many of these commercials instruct the viewer to "[s]ee our ad in *Money Magazine*." *Money Magazine* has a readership of approximately 7.6 million, of which approximately 5 million are men with a median male readership age of 44.5. Consistent with Lilly's television commercials, which also feature middle-aged men, Lilly's targeted DTC advertising in Money Magazine and elsewhere was designed specifically to attract middle-aged men with gradually declining, but non-hypogonadal age-appropriate testosterone levels.

191. Overall, the advertisements disseminated by Lilly have suggested that various symptoms often associated with other conditions may instead be caused by low testosterone and encouraged men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" included "decreased sexual desire (libido)," "erectile dysfunction," "fatigue and loss of energy," "depressed mood," "loss of body hair (decreased need to shave)," "decrease in strength," and "osteoporosis (decreased bone density)." All of these are general symptoms that are often a result of aging, weight gain, or lifestyle, rather than conditions associated with hypogonadism.

192. Lilly makes Axiron even more enticing to consumers and physicians by providing an easily downloadable "Savings Card" which can be used for a free 30-day trial and up to $75 in monthly savings on Axiron. The solicitation states: "Your eligible patients with commercial insurance get 1 year of monthly savings with the FIRST

MONTH FREE, and pay no more than $25 per month up to a maximum of $75 after the first month free." The website further encourages physicians to "Download as many as you'd like[.]" For consumers, card activation requires a simple clicking of three buttons: (1) that you are a resident of the United States or Puerto Rico; (2) that you are 18 years old; and (3) that your prescription is not covered by insurance through the government. Once the Savings Card is downloaded and activated, consumers are directed to show the Savings Card and prescription to the consumer's pharmacist. The Savings Card solicitation fails to mention any step regarding consultation with a physician and diagnosis of hypogonadism.

193. Lilly's sales representatives provided physicians and healthcare providers with information and literature concerning the indications for clinical use of Axiron, as well as discount and/or rebate coupons to give to patients for the purchase of Axiron.

194. Lilly's sales representatives detailed and marketed Axiron to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

195. Lilly denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

196. Lilly knew and understood the meaning of the terms "off-label" and "label expansion."

197. Lilly knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

198. Lilly marketed, promoted, and detailed TRT products for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, promoting the idea that "Low T" was an indication for clinical use of TRT products.

199. Acrux was at all times knowledgeable and complicit in Lilly's efforts to focus the marketing of Axiron on various off-label and unapproved uses. Acrux has publicized with approval its view that Lilly's marketing focus has been on "expanding the therapeutic indications for Axiron."

200. Acrux was hopeful that other off-label pursuits would materialize, stating "[t]here is scope for testosterone use in other indications such as cachexia, which is the muscle wasting and weight loss that occurs in the later stages of cancer." Acrux also stated that "[e]xploratory clinical studies have been publicized investigating testosterone effects in Alzheimer's and Multiple Sclerosis." Another slide also listed chronic opioid use, renal disease, Type II Diabetes, and obesity as potentially ripe markets for testosterone.

201. Acrux has profited richly on Lilly's off-label marketing and promotional efforts. Largely fueled by Lilly's success promoting Axiron, Acrux's stock soared 63% in one month alone in July 2014.

202. Acrux has actively worked to ensure that Axiron has gained improved access to both national and regional managed care formularies, which has propelled the use of Axiron by patients across the United States and worldwide.

203. Acrux assisted Lilly's effort to expand the indications for use of Axiron by promoting and detailing "Low T" as an acquired form of hypogonadism, and advantaged intentional ambiguity in the Axiron product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

204. The marketing and promotion of Axiron to patients and physicians overstated its benefits by creating the impression that it was a safe and effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

205. As a result of Lilly and Acrux's advertising and marketing, and

representations about their product, men in the United States pervasively seek out prescriptions for Axiron. If Plaintiffs and their physicians had known the risks and dangers associated with Axiron, the physicians would not have prescribed nor would Plaintiffs have taken Axiron and consequently would not have been subject to its serious side effects; and/or, Plaintiffs' physicians would have adequately monitored Plaintiffs' hematocrit and estradiol levels, and, as a result, Plaintiffs' injuries would have not otherwise have occurred.

206. At all times relevant, Acrux was aware of Axiron's propensity to cause thromboembolic, cerebrovascular and cardiovascular injuries. In fact, in its clinical trials for Axiron, Acrux excluded all patients which it believed were contraindicated for Axiron, which included patients with a documented history of thromboembolic disorders and patients with cerebrovascular and coronary artery disease. However, Acrux has made no effort to ensure these same contraindications appear in the product labeling for Axiron.

Endo's Off-Label Marketing

207. Endo also expanded the indications for use by promoting and detailing "Low T" as an acquired form of hypogonadism, and advantaged intentional ambiguity in their products' labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

208. In a late 2009 deal worth up to approximately $210 million, Endo acquired a license to commercialize Fortesta in the U.S. from ProStrakan Group, PLC of Great Britain. David Holveck, president and CEO of Endo, stated that Fortesta "is synergistic with our recent therapeutic expansion," which includes testosterone injection and testosterone implant products as well.

209. In August 2009, Endo entered into a License and Supply Agreement (the ProStrakan Agreement) with Strakan International Limited, a subsidiary of ProStrakan Group PLC (ProStrakan), for the exclusive right to commercialize Fortesta in the U.S.

210. Endo launched Fortesta in the first quarter of 2011. In a press release from January 5, 2011, Endo announced that the FDA had "approved FORTESTA Gel for the treatment of low testosterone, or 'Low T,' also known as hypogonadism."

211. In a March 3, 2011 press release, Endo further stated that the "introduction of FORTESTA Gel in the U.S. comes at a time when only about 1.3 million (9 percent) of the estimated 14 million men with Low T are actually receiving treatment."

212. The advertisements disseminated by Endo suggested that various symptoms often associated with other conditions may be caused by low testosterone and encouraged men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" included "reduced sexual drive (libido) and activity," "difficulty in achieving or maintaining an erection," feeling "tired, fatigued, or notice a loss of energy," depressed mood, "lost body hair or … less of a need to shave," "decrease in strength or muscle mass," or osteoporosis. All of these are general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

213. Endo's national education campaign included the creation and continued operation of the website www.GetTestedForLowT.com. The website asserts that many otherwise healthy men experience low testosterone and asks male visitors "Could You Be Living With Low Testosterone (Low T)?" Men are encouraged to complete a quiz to see if they are "eligible for a free testosterone test to measure [their] testosterone levels."

214. The "Could You Be Living with Low Testosterone (Low T)" quiz asks men if they suffer from the "symptoms" of low testosterone listed above. If a man indicates that he has at least two of these "symptoms," is over 35 years of age, has some form of health insurance, and does not live in New York, New Jersey, Rhode Island, Massachusetts or Maryland, they are directed to a website stating "You Qualify For a FREE Testosterone Test." They are then asked to provide some basic contact information so Endo can send them the paperwork for their free blood test.

215. Since the FDA approved Fortesta and Delatestryl for a very specific medical condition called hypogonadism, Endo has also sought to convince primary care physicians that hypogonadism is synonymous with "Low T" and that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

216. Despite the fact that the FDA has only approved Fortesta and Delatestryl for hypogonadism, Endo continues to market and promote testosterone replacement therapy for "Low T." One example is Endo's website, wherein Fortesta is promoted as a treatment for "Low T." See http://www.fortestagel.com/About-Low-T.aspx.

217. In a press release published on January 5, 2011, Endo announced that symptoms associated with "Low T" include "erectile dysfunction and decreased sexual desire."

218. In one 2011 direct-to-consumer ("DTC") campaign aimed at physicians, Endo ran ads in *Urology Times* and other periodicals with the banner "[h]elp replenish his testosterone levels with a low volume gel." This campaign used a gas station pump representation to show how Fortesta helps patients with testosterone deficiency "fill back up" and achieve normal testosterone levels. *Urology Times* has a circulation of over 11,000 urologists in the United States.

219. On December 27, 2011, Endo entered into a Sales and Promotional Services Agreement with Ventiv Commercial Services, LLC (Ventiv), effective as of December 30, 2011. Under the terms of the Ventiv Agreement, the Ventiv Field Force personnel promoted Fortesta, and its sales representatives were required to perform face-to-face, one-on-one discussions with physicians and other health care practitioners to promote these products.

220. In a 2012 ad that Endo ran in *Urology Times* and elsewhere which was aimed at urologists, the company showed two drops of Fortesta to represent two pump actuations on the front of the patient's thigh, and made the claim: "When his pair needs

some help, this pair could raise his T."

221. In another DTC advertisement, Endo used the tagline "Pump Up your T" to convince men that "If You're a Man With Low Testosterone (Low T), FORTESTA® Gel Could Help You." The ad claims that a "small amount of gel applied each day may be all that's needed to help raise your T."

222. Endo made testing for "Low T" even more enticing to consumers by providing free blood testing as long as state law did not prohibit it and the men indicated on an online questionnaire that they had at least two "symptoms" of "Low T."

223. In 2013, Endo spent more than 70% of its $13 million advertising budget for Fortesta on detailing physicians about Fortesta and "Low T."

224. Endo convinced hundreds of thousands, if not millions, of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Endo's promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

225. Endo manufactured, sold and promoted the drugs to treat a non-existent medical condition that it called "Low T," which was a name it created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, Endo marketed and sold testosterone as a lifestyle drug meant to make men feel younger and increase libido.

226. Endo's DTC enterprise sought to create the image and belief by consumers and their physicians that their products were safe methods of alleviating their symptoms that had few side effects and would not interfere with their daily lives, even though it knew or should have known these assertions to be false, and even though it had no reasonable grounds to believe them to be true.

227. Through its DTC enterprise, Endo purposefully downplayed, understated and outright ignored the health hazards and risks associated with using its products.

Endo deceived potential users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

228. Endo's advertising paid off in a return of $80 million in sales for Fortesta in 2012.

229. Endo engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T." The marketing program sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that the use of Fortesta and Delatestryl is safe for human use as a treatment for "Low T," even though Endo knew these to be false, and even though Endo had no reasonable grounds to believe them to be true.

230. At all times material hereto, Endo's marketing strategy included the use of sales or drug detailing representatives ("reps") and marketing and brand team personnel who performed on-line and in-person product detailing to physicians, and promotions and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

231. Endo's sales reps provided physicians and healthcare providers with information and literature concerning the indications for clinical use of their testosterone replacement therapy products, as well as discount and/or rebate coupons to give to patients for the purchase of those products.

232. Endo's sales reps detailed and marketed the products at issue to physicians as approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

233. Endo hosted numerous events where doctors trained and/or approved by Endo would falsely oversell the efficacy and safety of its testosterone products and would provide favorable information on the off-label use of these products, often under conditions where physicians would be compensated for attending the presentation. Endo funded and continues to fund scores of such events.

234. In fact, a report prepared by Encuity Research detailing the TRT promotional efforts in 2013 revealed that Endo, as a percentage of its total promotional budget, devoted a larger share of that budget toward "Meeting and Events" than did any other TRT manufacturer, including Lilly and AbbVie.

235. Endo created and controlled a Peer Selling Enterprise composed of medical marketing firms and several dozen physicians who routinely promoted its testosterone products to other physicians in venues all across the country. Endo selected and approved the content of the programs and the physician participants that would deliver the off-label messages. Physicians who were not receptive to promoting these off-label uses were not considered for inclusion. The physicians (mostly primary care physicians) who attended these events were deceived into thinking that the events were educational in nature and independent from the control of Endo.

236. Endo employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of its testosterone products for a variety of off-label uses; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of its testosterone products for both approved indications and for a variety of off-label uses; (c) deliberately concealing negative findings or the absence of positive findings relating to such off-label uses; (d)

wrongfully and illegally compensating physicians for causing the prescribing of its testosterone products; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of its testosterone products for both on-label and off-label uses, and then disseminating copies of such studies by the thousands; (f) intentionally misrepresenting and concealing Endo's role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell its testosterone products to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Endo and other participants in its Enterprises.

237. For example, Endo sponsored a CME-creditable supplement to the *Journal of Family Practice* with "an educational grant." The title of the CME program centered on so-called "Late-onset male hypogonadism" and the so-called learning objectives included "broadly classify[ing] late-onset male hypogonadism" and the targeted audience included "Family physicians" and primary care physicians "interest[ed] in treating patients with late-onset male hypogonadism." Of course, Delatestryl and Fortesta are not approved to treat "late-onset male hypogonadism" and are only approved to treat Primary hypogonadism and Hypogonadotropic hypogonadism. There is no indication for so-called "late-onset male hypogonadism," which is merely a synonym of "andropause" and the natural result of male aging. One of the faculty for this CME publication was Dr. Richard Sadovsky, who disclosed that he serves on Endo's advisory board, and the medical accuracy reviewer was Dr. Martin Miner, who is on the Auxilium speaker's bureau. Dr. Sadovsky received a $2,500 consulting fee payment on December 8, 2013 according to the CMS Sunshine Act database that recently went online.

238. In another example Endo sponsored an obviously off-label Testosterone Update CME titled "Hypogonadism and Erectile Dysfunction." The faculty for this June 2013 event was Dr. Allen D. Seftel, who disclosed that he was a consultant to

AbbVie, Actient, Auxilium, Endo, and Lilly. Dr. Seftel has received tens of thousands of dollars from these pharmaceutical companies, and the CMS Sunshine Act database reveals that Dr. Seftel received a $3,000 payment from Auxilium in November 2013 for "Food and Beverage" purposes. The event, which was organized by Endo through vendor participants Dannemiller and CogniMed, stated the following for its "Needs Assessment": "Hypogonadism and erectile dysfunction (ED) are under diagnosed and therefore undertreated conditions that can be associated with serious comorbid conditions, including metabolic and cardiovascular disease (CVD). Appropriate screening for comorbidities and treatment by any provider seeing men who are at risk should be encouraged. Mounting evidence indicates that ED and hypogonadism are associated with premature CVD, cardiovascular events, and cardiac death, as well as increased all-cause mortality. Despite compelling evidence, many clinicians are not aware of the connections between ED, hypogonadism, comorbid conditions, and overall health." The event, at Endo's direction and direct control, sought to convey the Endo marketing message concerning the purported link between ED and hypogonadism to each other and to other co-morbidities to encourage off-label use of Fortesta.

239. In another example, Endo supported with an "educational grant" an event organized by its vendor participants Postgraduate Institute for Medicine and Miller Communications, LLC, titled "Opioid-Induced Androgen Deficiency: Approaches to Diagnosis and Management." The title of the event explicitly promoted off-label use of Fortesta and other TRT drugs in chronic opioid users. All three faculty – Dr. Michael J. Brennan (consulting, speaker's bureau), Dr. Andre Guay (speaker's bureau, consulting), and Dr. Abraham Morgentaler (contracted research) – disclosed extensive financial connections to Endo. The event also falsely suggested that "[t]he opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of … Endo Pharmaceuticals, Inc." Endo sought to keep its extensive content control of programs, like the one described, secret.

240. Endo has promoted and marketed testosterone replacement therapy to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Endo overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

241. Endo has purposefully downplayed, understated and outright ignored the health hazards and risks associated with using its testosterone products. Endo concealed materially relevant information from potential users and their physicians, and minimized user and prescriber concern regarding the safety of its testosterone products, including but not limited to their known propensity to drastically increase hematocrit and estradiol levels in users.

242. Endo hired non-physician technical writers and used internal employees to create the necessary articles and then paid the specialists to be the articles' "authors." This practice is referred to as "ghostwriting." In order to monitor the status of publications, and in order to coordinate and execute the ghostwriting plan, marketing firms were necessary.

243. One particular example is the article by Dr. Adrian S. Dobs, *et al*., *A Novel Testosterone 2% Gel for the Treatment of Hypogonadal Males*, 33 J. ANDROL. 601-07 (2012). The article, which is the only study cited by Defendant Endo on its Fortesta healthcare professionals website for both safety and efficacy, purports to present the results of an independent study involving Fortesta's "novel" 2% testosterone gel for hypogonadal males. In fact, the true purpose of the article was to promote Fortesta on behalf of Endo. The facts and circumstances surrounding the creation of this study, which are outlined below, and its purpose were disclosed nowhere on Endo's Fortesta website.

244. The article discloses that the "study was funded by ProStrakan Pharmaceuticals, Inc." and that "[w]riting and editorial assistance was supported by

Endo Pharmaceuticals." These disclosures are misleading in that Endo did not just "support" the writing and editorial assistance. Endo controlled the content of the publication to ensure that the resulting article would support Endo's intended off-label marketing strategy.

245. As an initial matter, none of the so-called "external authors" disclosed any conflicts of interest, including Dr. Dobs, the lead (and thus cited) author. Two of the authors were ProStrakan employees and one was an Endo employee. Dr. Dobs has received thousands of dollars from TRT pharmaceutical interests over the years, and states on her Johns Hopkins faculty profile that she has "published extensively" on the "risks and benefits of testosterone replacement therapies." According to the CMS Sunshine Act physician payment database, Dr. Dobs, less than a year after publication of this study, received a $3,000 "consulting" payment from Endo. Payments to Dr. Dobs from Endo prior to August 2013 will be explored in discovery. However, Dr. Dobs has received tens to hundreds of thousands of dollars of pharmaceutical interests' money over the years, including from Endo. Most of Dr. Dob's TRT publications center on the benefits of off-label use.

246. While Endo hired doctors to serve as "authors" of the study in order to support the perception that this article was an independent and scientific publication, Endo also took significant steps to ensure that the resulting product presented a message Endo could promote to potential prescribing physicians. After the article's favorable discussion of TRT drugs and of Fortesta as a result of the Endo-funded study, the authors "thank Peter Budka and Catherine Jones (Watermeadow Medical) for their writing and editorial assistance."

247. Watermeadow, an Endo vendor participant, is a medical communications firm that specializes in "Excellence in Medical Communications," publication planning and development, advocacy development and medical education. It has been retained by multiple pharmaceutical companies to promote their respective products, including

Endo Pharmaceuticals for Fortesta.

248. Under the "Scientific Publications" section of its website, Watermeadow states that "[i]nfluential, informative and accurate scientific publication writing underpins all clinical, marketing and sales activities." Under the "Publication planning" section of its website, Watermeadow opens with, "[p]ublication planning is vital to the success of the marketing strategy of any product." Watermeadow also notes that scientific publications are "one of the most influential communication channels for healthcare and scientific audiences." Of course, such channels are influential only when the articles appear to be the result of unbiased research by specialist researchers at teaching universities, such as Dr. Dobs at Johns Hopkins. While most medical writing firms are more discreet about their value to their clients, Watermeadow has understood, and stated on its website that it understood, that Endo intended that and would in fact be using the Dobs et al. article for promotional and sales purposes.

249. Watermeadow's own promotional materials emphasize that its employees will "be working directly with clients" in an effort to "unite scientific and creative flair to maximise the communication of your key messages to the people who matter," and "deliver striking and influential communications that will set you apart from your competition." In an employment brochure describing a day in the life of "Jane," who is a more or less fictional Watermeadow medical writer, "Jane has a sandwich and a chat with colleagues in the communal area at lunchtime, then returns to her desk to go through a draft manuscript which a senior writer has reviewed for her and corrected using tracked changes. Going through them, Jane realizes that the senior writer has filled in some gaps in the discussion and also improved the structure. She makes a mental note of what she needs to do differently next time." Interactions with the study "authors" as denoted on the final published product appear not to be a part of Jane's normal day as a medical writer.

250. Watermeadow's employment brochure emphasizes the importance of

medical writers and medical editors to its efforts. The brochure quotes a medical writer who states, "I choose to work for Watermeadow because it allows me to use my scientific background in a more creative way." However, a scientific background is not required to be employed as a medical writer or editor, and apparently was not in the Dobs et al. article created by Watermeadow at Endo's direction. One of the Watermeadow employees who was thanked in the Dobs article for his "writing and editorial assistance," Peter Budka, holds a B.A. in English Literature and Classics. Defendant Endo and Watermeadow understood that a publication authored by Mr. Budka would not be as influential as a publication by Dr. Dobs, which is why Dr. Dobs was paid for her "authorship" of the study.

251. Endo used the efforts of Watermeadow and others to control the misleading messages it promoted. These efforts gave the impression that their products were supported by independent science, which allowed them to conceal the serious risks, including cardiovascular health, associated with TRT therapy.

252. Endo created study protocols consistent with Endo's intended off-label marketing messages, funded these studies to completion, exercised total control over the decision to publish and the format and substance of the resulting medical journal articles, and paid largely through its vendor participants prominent physicians to lend their names for "authorship" of such articles in exchange for handsome payments. Endo then masqueraded these predetermined study results, often ghostwritten by Endo and its vendor participants, as credible science on its websites, through reprints distributed by Endo's sales force to physicians, and through physician speakers.

253. Endo denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

254. Endo knew and understood the meaning of the terms "off-label" and

"label expansion."

255. Endo knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

256. Endo marketed, promoted, and detailed Fortesta and Delatestryl for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, promoting the idea that "Low T" was an indication for clinical use of the Fortesta and Delatestryl products.

Auxilium's and GSK's Off-Label Marketing

257. Auxilium also expanded the indications for use of these testosterone replacement therapy products by promoting and detailing "Low T" as an acquired form of hypogonadism.

258. Auxilium promoted and marketed to its investors, consumers, patients, physicians, and other healthcare providers that there was an epidemic of untreated hypogonadism in the U.S. affecting 20% of the older male population.

259. Auxilium sought (and, as the current owner of Testim, Testopel, and Striant, Endo still seeks), to take advantage of normal male pattern physiologic responses to aging as a market entry strategy, marketing opportunity, and sustained conduit for revenue and profit growth potential.

260. Auxilium expanded its portfolio of testosterone-containing medications to include Testim, Striant, and Testopel, and markets and promotes these products as treatments for "Low T."

261. Auxilium marketed its TRT products in the United States through its own marketing, advertising, and branding teams; and through consultants, marketing firms, agencies, organizations, and other pharmaceutical companies external to Auxilium.

262. At all times material hereto, Auxilium's marketing strategy included the use of sales or drug-detailing sales representatives ("reps") and marketing and brand

team personnel who performed or arranged:

a. on-line and in-person testosterone product detailing to physicians;

b. promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths and industry presentations;

c. "satellite" meeting sessions performed by physicians paid or sponsored by Auxilium; and

d. sponsored medical speakers.

263. The Auxilium sales reps provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the testosterone products, as well as discount and/or rebate coupons to give to patients for the subsequent purchase of the these products.

264. Auxilium sales reps detailed and marketed testosterone products to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms. Auxilium also marketed its testosterone products to pharmacists.

265. Auxilium, among other testosterone product manufacturers, recruited and financially engaged a cadre of "thought leaders," "key opinion leaders," and industry funded speakers, including individuals with leadership positions in influential scientific organizations and societies (*e.g.*, the Endocrine Society and the American Urological Association) to offer opinions which supported, advocated, and encouraged "off-label" clinical indications for testosterone therapy.

266. Auxilium engaged "thought-leaders," "key opinion leaders," and medical consultants, including Dr. Abraham Morgantaler from Harvard University, who was a member of Auxilium's Scientific Advisory Board; and Dr. Francis Hayes from Harvard University and the Massachusetts General Hospital, who was a co-author of the 2010 Endocrine Society testosterone guidelines, *Testosterone Therapy in Adult Men with*

Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline, to influence physicians concerning the diagnosis of "Low T" and the benefits of testosterone replacement therapy for the treatment of age-related declines in testosterone levels and age-related symptoms in men. These physicians aggressively condoned and advocated "off-label" and unapproved uses for the testosterone products.

267. Through its advertising and promotional campaigns, including physician detailing and direct-to-consumer advertising, Auxilium denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker or designator to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

268. Auxilium knew and understood that testosterone replacement therapy was never approved by the FDA for "off-label" promotion, or for the treatment of "Low T" as a clinical indication for use.

269. Auxilium engaged in "label expansion" in both its promotion of it testosterone replacement therapy products to physicians and in its marketing of these products to consumers and patients.

270. Auxilium engaged in direct-to-consumer marketing, promotional, and comprehensive educational campaigns through a variety of educational, advertising, and informational multimedia platforms, including Internet-based dedicated "Low T" and dedicated testosterone product websites.

271. Auxilium well understood the importance of its DTC advertising in creating a market for off-label use of TRTs. In its 2012 Annual Report to investors, Auxilium stated that "the U.S. market will continue to expand based on disease education programs and increasing patient disease awareness, driven in part by national 'direct-to-consumer' television and Internet advertising campaigns focused on

adult males with low testosterone." Thus, Auxilium admitted that its focus was "adult males with low testosterone," rather than men with hypogonadism, and it further acknowledged the role its disease-mongering and DTC campaigns had in generating sales of its TRT products.

272. Age-related declines in men's testosterone levels and age-related symptoms are not categorized as a "disease" for which testosterone replacement therapy was an FDA-approved indication for clinical use.

273. At all times material hereto, Auxilium undertook to educate consumers and patients concerning "Low T" as a "disease" by providing specific misinformation regarding the diagnosis and treatment of "Low T," and portraying "Low T" as a "disease" subsumed under the medical category of acquired hypogonadism. This was undertaken in a concerted effort to drive treatment-demand and increase physician prescribing habits for the testosterone products for the economic and financial benefit of Auxilium.

274. As described below, Auxiliums's advertising campaigns for its TRT products included, *inter alia,* an unbranded "Low T Facts" campaign; "The Shaun Micheel Story" campaign; the "Level Up Plan" for Testim; the "Low Testosterone Therapy With Testim" campaign; and the "Reclaim Your Life" campaign for Testopel.

275. Auxilium's advertising campaigns, including, in particular its unbranded and "disease awareness" campaigns were intended to, and did, promote sales of all three of Auxilium's TRT products, Testim, Testopel, and Striant.

276. In 2003, Auxilium developed a marketing strategy to increase consumer and physician targeting and to achieve greater sales efficiencies by working with educational groups, including "Everyday Health," "Hormone.org," and "MensHealthNetwork" with respect to its testosterone products.

277. In 2006, Auxilium and Oscient Pharmaceuticals Corporation ["Oscient"] signed a co-promotion partnership to promote Auxilium's Testim product in the U.S. to

a significantly larger group of primary care physicians beyond those already called upon by Auxilium detailing personnel and sales reps.

278. Under the terms of the co-promotion agreement with Oscient, Oscient would promote Testim to primary care physicians using its 250-person sales force. At the time, the Oscient salesforce was active in the promotion of Oscient's FACTIVE® (gemifloxacin mesylate) tablets.

279. Auxilium's sales force continued to promote Testim to urologists, endocrinologists, and select primary care physicians using its own specialty sales force and sales reps.

280. Auxilium and Oscient agreed to share the profits from primary care sales above a pre-determined baseline after marketing expenses were reimbursed. The co-promotion partnership had an initial term of two years, with the potential for extension for up to six years duration, pending achievement of mutually agreed upon milestones.

281. Auxilium and Oscient projected the budget for marketing and promotion of Testim in the primary care physician market in the United States to be approximately $10.5 million in 2005 and approximately $13 million in 2006.

282. Auxilium and Oscient knew that that they were entering into an agreement with an intent to conduct "off-label" promotion for clinical use, and "label expansion" of Testim.

283. In 2006, Auxilium retained Lathian Health ["Lathian"], a provider of pharmaceutical marketing services and technology-based sales solutions, to perform "ePromotion" and "eBrand Messaging" programs on behalf of Auxilium with respect to Testim.

284. Lathian recruited 150 physicians to participate in an on-line branding campaign for Testim, which then enabled Auxilium's Testim branding and marketing teams to select a broader promotional campaign directed towards an expanded number of physicians for the purpose of increasing and promoting "off-label" prescriptions for

Testim.

285. The goal of the "ePromotion" program was to use Lathian's "Virtual Detailing" to increase physician prescribing habits with respect to Testim among a group of 25,000 targeted physicians.

286. At the corporate level, the "ePromotion" strategic initiative was undertaken to improve Auxilium's "top-line" revenues and "bottom-line" earnings generated from sales of Testim, and to increase market share of Testim in the testosterone replacement therapy market.

287. The "ePromotion" strategic initiative relied upon promoting Testim to physicians for the treatment of age-related declines in testosterone levels and age-related symptoms in men, thereby encouraging "off-label" prescribing and "label expansion" with respect to the Testim product's clinical uses.

288. In or before 2010, Heartbeat Ideas, a full service digital marketing agency, together with and on behalf of Auxilium, initiated advertising Auxilium's "Low Testosterone Therapy With Testim" campaign.

289. In 2011, Auxilium's "Low Testosterone Therapy With Testim" advertising campaign received awards from the Pharmaceutical Executive's Ad Stars and the DTC Perspectives National Ad Awards.

290. On October 13, 2011, Auxilium announced "that the company's low testosterone awareness campaign, Low T Facts, was recognized as the "Best Interactive Initiative for Consumers" at the 2011 Medical Marketing & Media (MM&M) Awards."

291. In their award submission for the unbranded "Low T Facts" campaign, which was undertaken on behalf of and for the benefit of Auxilium, Heartbeat Ideas acknowledged that "[t]he target audience for this campaign was 50-64 year old men *who have not been diagnosed with low testosterone*, but have the symptoms of low testosterone." (Emphasis added.) According to the submission, these symptoms include "reduced sexual function, desire and performance, low energy or fatigue, bad mood or poor

concentration, reduced muscle mass/strength and increased body fat, which are often attributed to other conditions." The ads were designed to "dr[i]ve users to www.lowtfacts.com for additional information on symptoms and a branded treatment solution."

292. Auxilium knew that "reduced sexual function, desire and performance, low energy or fatigue, bad mood or poor concentration, reduced muscle mass/strength and increased body fat, which are often attributed to other conditions" were not, and never have been, the FDA-approved indications for clinical use of the testosterone replacement products.

293. The submission thus makes clear that Auxilium was well aware that the "Low T Facts" campaign was designed to market Testim for off-label uses unrelated to the medical condition hypogonadism.

294. Auxilium also retained the "Transit Creative Brand Design Group" to formulate and design a consumer marketing strategy and marketing plan with respect to Testim.

295. The "Transit Creative Brand Design Group" formulated a marketing plan which provided men with educational and medical informational materials about Testim.

296. The "Transit Creative Brand Design Group" marketing plan included a celebrity testimonial and endorsement from United States Professional Golf Association (PGA) golfer Shaun Micheel, who the endorsement stated had been "successfully" treated for "Low T" with Testim, which the plan touted, provided Micheel "More support . . . to help him be more himself."

297. The Auxilium website featuring "The Shaun Micheel Story" and "Shaun's experience with Low T" offered consumers and patients:

a. "Education about Low T";

b. an "Interactive ADAM Questionnaire";

c. "Comprehensive disease-state information"; and

d. a "Physician Finder" service to assist patients in finding physicians who were prescribing Testim therapy for the treatment of "Low T."

298. Auxilium referred patients for evaluation of "Low T" to high-prescribers of Testim.

299. Auxilium's "Interactive ADAM Questionnaire" referenced in the Shaun Micheel endorsement website for the Testim product invited consumers to visit an Internet site designed to self-screen and self-assess for "Low T" signs and symptom patterns. This was the same ADAM questionnaire descrbied above, which was developed by Dr. John E. Morley and used by AbbVie and other TRT manufacturers.

300. The "Interactive ADAM Questionnaire" referenced in the Shaun Micheel endorsement website provided criteria for the diagnosis of "Low T," and a scoring system for signs and symptoms as they relate to the diagnosis of "Low T."

301. The "ADAM Questionnaire" provided a "Low T" scoring system to assist men in self-screening and self-diagnosing the predicate signs and symptoms for the diagnosis of "Low T."

302. Rather than screening for hypogonadism, the "ADAM Questionnaire" screened for age-related signs and symptoms. The signs and symptoms screened for in the "ADAM Questionnaire" are not FDA-approved clinical indications for androgen therapy, including therapy with the Testim product.

303. The "Interactive ADAM Questionnaire" on the Testim website further provided a mechanism for a consumer or patient, without a physician intermediary, "[t]o order a home-saliva test" for further self-diagnostic testing for "Low T."

304. The Shaun Micheel endorsement website afforded consumers a means to self-diagnose "Low T" through a self-assessment diagnostic questionnaire and potential in-home testosterone testing.

305. The Shaun Micheel endorsement website afforded consumers a means to

be referred to or gain access to a physician, who was known by Auxilium to treat "Low T" and to prescribe the Testim product, with Auxilium as the referral source and referring intermediary.

306. Auxilium advised and urged men to self-diagnose "Low T" via a checklist of age-related signs and symptoms, and to further perform in-home diagnostic laboratory testing to assist in confirming the diagnosis of "Low T."

307. Auxilium provided assistance with insurance coverage issues, denials, or problems arising out of the prescription or potential prescription of Testim therapy through the Testim Access Hotline.

308. Auxilium knew and understood that the promotion of "off-label" indications for the use of the Testim product would create insurance or third-party payer coverage issues and problems for patients.

309. Auxilium knowingly promoted Testim and its other testosterone products to physicians as being a treatment for the conditions set forth on the "Interactive ADAM Questionnaire."

310. Auxilium engaged in aggressive promotion and detailing to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions set forth on the "Interactive ADAM Questionnaire."

311. Auxilium also promoted Testim with something it called the "Level Up Plan" on its Testim website. The "Level Up Plan" was undertaken to drive men to seek "Low T" treatment with "off-label" prescriptions for Testim.

312. As set forth on Auxilium's dedicated Testim website, the "Level Up Plan" solicited Protected Health Information (PHI) from patients who were clearly identified by their name, address (including email address), and date of birth, including current medication profile ("I am currently being treated with Testim"); and whether patients were currently diagnosed with "Low T" ("I do not intend on treating my Low T in the immediate future. . . ."). The "Level Up Plan" was framed as "Whether you're ready to

treat your Low T or not," rather than as "Whether your doctor is ready to treat your Low T or not."

313. Auxilium knew that physician prescription practices with respect to the Testim product were heavily influenced by and driven by consumer demand for the testosterone treatment, and that patients were in fact deciding whether they would be treated with testosterone-containing products for their "Low T."

314. The "Level Up Plan" acknowledged the central and pivotal role of consumer choice and product demand with respect to Testim treatment and usage, and the fact that consumer acceptance of Testim treatment was a key driver of product sales, revenues and earnings growth, and prescription demand.

315. Auxilium's ""Level Up Plan" offered to provide consumers with on-going medical information concerning Testim in order to further "educate" men with respect to the product, and to assist men in obtaining Testim treatment.

316. The "Level Up Plan" shows that Auxilium knew and understood that consumers were looking to Auxilium for and reasonably and justifiably relied upon Auxilium to provide, true, accurate, and correct information to assist in their choice concerning use of the Testim product.

317. The "Level Up Plan" and the Testim website provided consumers with the opportunity for a continuing and ongoing relationship directly with Auxilium, and without an intervening physician, with respect to the Testim product.

318. Auxilium's "Level Up Plan" website offered consumers and patients an opportunity for ongoing medical information from and dialogue with Auxilium concerning the Testim product and "Low T" in order to provide men with "information most relevant to [their] specific needs."

319. A patient's "specific needs" were ascertained via the solicitation of Protected Health Information (PHI) by Auxilium.

320. Auxilium's "Level Up Plan" and Testim websites were crafted to establish

an ongoing interactive and comprehensive medical, educational, and informational "consumer-pharmaceutical company relationship" in order to drive demand for "Low T" testing and self-diagnosis to stimulate and increase consumer demand for "off-label" treatment with Testim.

321. Auxilium's "Level Up Plan" and Testim websites knowingly provided consumers and patients with misinformation concerning the FDA-approved indications for clinical use of the Testim product, and were designed to establish, expand, and advantage an internet-cultivated consumer base for the purpose of driving Auxilium's revenues, earnings, and market share in the Testim product space through "off-label" prescription and product use.

322. Auxilium assumed and undertook duties separate and apart from, but coterminous with, roles traditionally reserved for and undertaken by healthcare providers, including:

a. offering consumers and patients extensive medical information concerning a "disease," including signs, symptoms, etiology, and associated co-morbidities;
b. advising patients concerning the treatment and/or treatment options for that "disease";
c. providing assistance in the diagnosis of the "disease" by taking a detailed history of patient signs and symptoms, and recommending or directing laboratory testing for the "disease";
d. providing information about specific drug therapy for the "disease"'
e. providing patients with physician referrals for evaluation and treatment;
f. soliciting Protected Health Information (HPI) and data concerning the health status of patients, including prior or current signs and symptoms; and
g. Maintaining an ongoing and relationship with the patient to provide

further medical information.

323. Throughout its marketing and branding campaigns for Testim, Auxilium provided consumers and patients with comprehensive medical advice, diagnostic information, and explanations of specific medical diagnostic criteria and medical terminology.

324. Throughout its marketing and branding campaigns for Testim, Auxilium provided consumers and patients with, and directed consumers and patients to, "Low T" medical self-screening and self-diagnosis materials.

325. In 2010, Auxilium engaged the marketing services of "e-tractions," a web-based marketing solutions provider, to optimize the web-based Testim marketing campaign.

326. As described by e-tractions, there were four objectives for the campaign. The first was to drive traffic to www.testim.com in order to create greater awareness and understanding of hypogonadism and Testim in particular. The second was to encourage registrant to download a rebate coupon to stimulate demand. The third was to collect names and email addresses of registrants so that Testim could communicate with registrants through permission-based emails on a regular basis. And lastly, the goal was to use the registration as a means to better understand the demographic and behavioral profile of potential Testim patients.

327. According to e-tractions, the nine-month online marketing campaign generated a database of over 260,000 names and email addresses of men who gave permission for Testim to communicate with them via email. Both traffic to testim.com and registrations on the site increased significantly, with more than 30% of those who responded to the online advertising downloading a Testim rebate offer.

328. As was true with its "Level Up Plan," Auxilium solicitied Protected Health Information (PHI) via "relationship marketing emails" including patient information concerning "erectile dysfunction and type 2 diabetes." Neither of these

conditions were clinical indications for Testim therapy. Auxilium thus sought to drive patient demand for the Testim product on the front end, and to increase physician prescribing habits for Testim on the back end, to improve Auxilium's revenues and market share in the TRT product market.

329. Auxilium promoted Testopel with a "Reclaim Your Life" campaign that portrayed Testopel as a remedy for aging. The Testopel website that promoted this campaign prominently featured a quotation from Oliver Wendell Holmes: "Men do not quite playing because they grow old; they grow old because they quit playing." The Testopel website claimed that "common symptoms of Low T" included depression, erectile dysfunction, and Type II Diabetes. The website asked men "Do you have Low T?" and encouraged them to "Take the Quiz."

330. Auxilium's predecessor-in-interest, Slate, received a "Warning Letter" from the FDA DDMAC dated March 24, 2010 concerning the "Reclaim Your Life" campaign and in particular, certain web pages and a consumer video on the Testopel website. The FDA found that the pages and the video were misleading because, *inter alia,* they "promote unapproved uses of Testopel" and because they "broaden the indication for Testopel." The FDA noted in its warning letter: "The overall impression conveyed by the above claims misleadingly implies that Testopel can be used to treat the symptoms of depression, erectile dysfunction, type 2 diabetes, HIV, mood disorders, and loss in sexual interest, and that Testopel treatment results in an increase in muscle mass and bone strength. FDA is unaware of any data to support these claims and implications."

331. Dr. Abraham Morgantaler, the physician discussed in the 2010 "Warning Letter" to Slate, was and remains a member of Auxilium's Scientific Advisory Board since 2004.

332. Although the current Testopel website no longer includes the Holmes quotation, the site still lists as symptoms of "Low T" such conditions as "decreased

energy, motivation, and self-confidence"; "[f]eeling sad or blue"; "[p]oor concentration/memory"; "[s]leep disturbance, increased sleepiness"; "[r]educed muscle bulk and strength"; "[i]ncreased body fat, body mass index"; and "[d]ecline in physical or work performance," even though none of these are specific to hypogonadism or low testosterone as a result of a clinical disease or condition.

333. Auxilium denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

334. Auxilium knew and understood the meaning of the terms "off-label" and "label expansion."

335. Auxilium knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product. Indeed, Auxilium received numerous warning letters from the Division of Drug Marketing, Advertising and Communications ["DDMAC"] concerning the content of their advertising and promotion of its TRT products.

336. Auxilium marketed, promoted, and detailed Testim, Testopel, and Striant for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, promoting the idea that "Low T" was an indication for clinical use of the TRT products such as Testim, Testopel, and Striant.

337. On or about May of 2012, Auxilium entered into a co-promotion agreement with GlaxoSmithKline ("GSK") for the purpose of expanding the physician marketing, detailing, and promotion efforts for Testim in the United States. Under the terms of the agreement, Auxilium granted GSK the exclusive right to co-promote the sale of Testim with Auxilium in the U.S. through September 30, 2015. GSK will promote

Testim using a sizeable established field sales force which has relationships with current TRT prescribers, particularly primary care physicians, in the U.S. These GSK sales representatives currently promote a range of cardiovascular, metabolic and urology products, and Testim will complement GSK's existing portfolio of products.

338. Auxilium and GSK agreed on a baseline revenue forecast for Testim through September 30, 2015, and agreed that GSK would be compensated to the extent that Testim net sales exceed this baseline. In addition, in certain circumstances, Auxilium would pay GSK specified tail payments following the term of the agreement. The GSK sales force was expected to begin promoting Testim to physicians early in the third quarter 2012. Auxilium was to remain responsible for all Testim commercial drug manufacturing, supply, and regulatory activities.

339. In providing for "tail" payments following the term of the agreement, GSK and Auxilium recognized that, in at least some circumstances, the effects of GSK's efforts in marketing and promoting Testim would persist even after the agreement had terminated, and that, in particular, prescribers "sold" on Testim by GSK and its sales force would in all likelihood continue to prescribe Testim, or other TRT products, even after GSK sales reps no longer met with them to promote it.

340. Auxilium and GSK knew that that they were entering into an agreement to conduct "off-label" promotion for clinical use and "label expansion" of the Testim product.

341. On or about August 1, 2013, the co-promotion agreement between GSK and Auxilium was mutually and prematurely terminated approximately two years prior to the projected and scheduled end-date of September 30, 2015.

342. During the life of the co-promotion agreement, GSK participated and played a role in the selling and distribution of Testim.

343. During the life of the co-promotion agreement, GSK, along with Auxilium, conducted "off-label" detailing and promotion of Testim to physicians, and

misrepresented to physicians that Testim was an FDA-approved treatment for "Low T" and age-related declines in testosterone levels and age-related symptoms in men.

344. During the life of the co-promotion agreement, GSK knew and understood that the male aging process is not an acquired form of hypogonadism, and that declines in testosterone levels are a physiologic response during male aging.

345. During the life of the co-promotion agreement, GSK made false, deceptive, inaccurate, and misleading statements and claims to physicians and healthcare providers regarding the clinical safety and effectiveness profiles of Testim, and Testim's spectrum of FDA-approved indications for clinical use.

346. As co-promoter, GSK not only engaged in off-label marketing of Testim along with Auxilium, it was also obliged, and failed, to disclose to physicians and consumers the risks of TRT products, as described in detail below.

347. GSK denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

348. GSK knew and understood the meaning of the terms "off-label" and "label expansion."

349. GSK knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

350. GSK marketed, promoted, and detailed Testim for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, promoting the idea that "Low T" is synonymous with hypogonadism and that Testim is approved and indicated for clinical use in treating "Low T."

Pfizer's Off-Label Marketing

351. Pfizer similarly expanded the indications for use by promoting and

detailing "Low T" as an acquired form of hypogonadism, and took advantage of intentional ambiguity in the Depo-Testosterone product labeling as a basis for "label expansion" and "off-label" marketing, detailing, and promotion to physicians.

352. Pfizer's promotion of Depo-Testosterone focused primarily on physician detailing and marketing designed to convince physicians that hypogonadism is synonymous with "Low T" or low testosterone and that Depo-Testosterone was the best option for treating "Low T."

353. Through physician detailing, Pfizer purported to educate physicians about low testosterone and their solution (Depo-Testosterone) to the condition.

354. Pfizer engaged in aggressive promotion to physicians that testosterone replacement therapy could be used as a lifestyle drug to treat conditions such as erectile dysfunction. Sales representatives were instructed to tell physicians that if a patient requested medication for erectile dysfunction the physician should first test the patient's testosterone level to determine if the cause of the erectile dysfunction was "Low T."

355. At all material times, Pfizer's marketing strategy included the use of sales or drug detailing representatives ("reps") and marketing personnel who performed on-line and in-person TRT product detailing to physicians; and, promotional and detailing to healthcare providers and physicians at medical organization and society meetings and conventions via display booths, sponsored meeting sessions and "satellite" sessions, and sponsored medical speakers.

356. Pfizer's drug-detailing reps provided physicians and healthcare providers with information and literature concerning the indications for clinical use of the Depo-Testosterone product, as well as discount and/or rebate coupons to give to patients for the purchase of Depo-Testosterone.

357. Pfizer's drug reps detailed and marketed Depo-Testosterone to physicians as a product approved and indicated for the treatment of age-related declines in testosterone levels and age-related symptoms.

358. As part of its advertising campaign, Pfizer operates websites designed to market Depo-Testosterone to physicians. Pfizer's sales force directed physicians to access these websites to better educate themselves on "Low T" and Depo-Testosterone.

359. Pfizer's marketing to doctors blurs the line between Depo-Testosterone's approved indications and "Low T." For example, Pfizer asserts Depo-Testosterone has been used for more than 30 years in "the treatment of males with low testosterone," when in fact Depo-Testosterone is approved for treating hypogonadism, not low testosterone.

360. Because the FDA approved Depo-Testosterone for a very specific medical condition called hypogonadism, Pfizer sought to convince primary care physicians that hypogonadism is synonymous with "low testosterone" and that low testosterone levels are widely under-diagnosed, and that normal and common conditions associated with normal aging could be caused by low testosterone levels.

361. By saying their product has been used for decades, Pfizer also implies that its product is safe for treatment of men with "low testosterone" (rather than men with hypogonadism) based on over 30 years of clinical use.

362. Pfizer also coordinated an advertising campaign targeted toward men who did not have hypogonadism, nor had low or no testosterone in conjunction with an associated medical condition. Pfizer designed its direct to consumer marketing to convince men they suffer from a non-existent and unrecognized medical condition called "Low T."

363. As part of its advertising campaign, Pfizer operates a website to market Depo-Testosterone to consumers: http://www.pfizer.com/products/product-detail/depo_testosterone.

364. Pfizer also benefited from competitors' efforts that suggest various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if

they experienced any of the "symptoms" of low testosterone. These "symptoms" include decreased muscle, spontaneous erections, and sexual motivation and desire, as well as increased body fat and fat mass-all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

365. To take advantage of other TRT makers' disease awareness campaigns, Pfizer's marketing actively blurs the line between Depo-Testosterone's approved indications and "low testosterone." For example, Pfizer's Depo-Testosterone website starts with the following come-on:

> Men, if your testosterone is low, there's something you should know . . .
>
> There's a prescription medication that is: Used to treat males over age 12 who have low or no testosterone. . . . Ask your doctor about Depo-Testosterone

366. The advertisement makes no mention of hypogonadism and suggests that Depo-Testosterone is indicated for the treatment of low testosterone. This impression is reinforced by the use of the tag-line "Used for more than 30 years in the treatment of males with low testosterone," which follows immediately after the suggestion to "As your doctor."

367. Pfizer sought to create the image and belief by consumers and physicians that low testosterone was an actual disease or medical condition that affected a large number of men in the United States, and that using TRT is safe for human use as a treatment for "Low T," even though Pfizer knew these to be false, and even though Pfizer had no reasonable grounds to believe them to be true.

368. In order to ensure physicians were more likely to prescribe and consumers were more likely to purchase Depo-Testosterone, Pfizer offered financial assistance in obtaining Depo-Testosterone prescriptions through Pfizer RxPathways. Consumers without insurance coverage for Depo-Testosterone were informed that they may be eligible for savings on Depo-Testosterone through Pfizer's RxPathways Savings Card

program which saved an estimated 15% - 75% for the prescriptions.

369. Pfizer denominated and characterized age-related declines in testosterone levels and age-related symptoms in men as "Low T," and used the "Low T" moniker to denote and connote that the presence of age-related declines in testosterone levels and age-related symptoms in men were a form of acquired hypogonadism.

370. Pfizer knew and understood the meaning of the terms "off-label" and "label expansion."

371. Pfizer knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

372. Pfizer marketed, promoted, and detailed Depo-Testosterone for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to physicians, and advertised the product to consumers and patients, promoting the idea that "Low T" is synonymous with hypogonadism and that Depo-Testosterone is approved and indicated for clinical use in treating "Low T."

Actavis's Off-Label Marketing

373. After the FDA approved Androderm in 1995, Actavis engaged in media campaigns to convince men who were experiencing the typical effects of the aging process that they were suffering from low testosterone, which could be treated with testosterone supplements, including Androderm. The marketing campaign consisted of advertisements, promotional literature placed in healthcare providers' offices and distributed to potential Androderm users, and online media including at least three websites devoted to convincing patients and their doctors to use Androderm.

374. Actavis uses a broad spectrum of marketing tools to drive Androderm interest and sales from men seeking general information, from men who are already interested in competing products, and from doctors making prescribing decisions.

375. One of the websites Actavis operates is an unbranded website, www.myTlevel.com, which purports to be a neutral, informational site and has no

mention of Androderm. Viewers who are persuaded they need TRT and click on the "Available Treatment" link are led to MyAndroderm.com, one of Actavis's branded websites.

376. The unbranded, myTlevel site greatly expands the approved indications for TRT products, and in particular, Androderm. The website tells men that "[t]estosterone deficiency can be associated with a variety of symptoms, including fatigue, depression, decreased libido, impotence, and decreased muscle mass." It tells men they can "confirm the diagnosis" by answering the ADAM questionnaire, the same questionnaire used by other TRT manufacturers.

377. Actavis's ADAM questionnaire asks men such questions as:

Do you have a decrease in libido (sex drive)?

Do you have a lack of energy?

Do you have a decrease in strength and/or endurance?

Have you noticed a decreased "enjoyment of life"?

Are you sad and/or grumpy?

Are your erections less strong?

Have you noted a recent deterioration in your ability to play sports?

Are you falling asleep after dinner?

The website presentation of the ADAM questionnaire prompts men by placing the word "YES" in capital letters next to each question. The website instructs men "if you answered 'Yes' to any 3 questions in total, you may wish to talk to your doctor about having a blood test to determine your testosterone level."

378. In fact, the symptoms listed on Actavis's ADAM questionnaire are virtually all symptoms of normal aging in middle-aged and older men. Actavis's myTlevel website suggests, however, that a man with any three of these symptoms is a

candidate for testosterone replacement therapy. In this way, Actavis seeks to expand the indication for Androderm and engages in off-label marketing of its TRT product.

379. Actavis also operates a consumer-oriented branded website called www.MyAndroderm.com that is dedicated to recruiting patients and marketing directly to consumers. MyAndroderm.com provides a list of potential "symptoms" of low testosterone. The symptoms listed include "decreased strength," "tiring easily," "increased body fat," "depressed mood," "emotional 'ups and down,'" "irritability," and "decreased energy."

380. Ignoring proper diagnostic procedures, Actavis's MyAndroderm website tells men that "diagnosis is simple," and that "low testosterone is diagnosed through a simple blood test."

381. Actavis also actively sought to capitalize on its competitor's marketing campaigns by selling Androderm as a safer alternative to other TRT products. Its Internet advertising asked men if they are a "High Five Type of Guy," a "Bear Hug Type of Guy," or a "Firm Handshake Type of Guy" and portrayed Androderm as safer because, the advertisements suggested, the user will not transmit the drug to co-workers, children, and friends.

382. Through another branded website targeted at health care professionals, (www.Androderm.com), Actavis encouraged doctors to "Think Beyond the Gel" and advertised that because the Androderm patch would "keep [the testosterone] contained," it was safer than other TRT products.

383. Actavis knew and understood the meaning of the terms "off-label" and "label expansion."

384. Actavis knew and understood the FDA regulations pertaining to "off-label" marketing and promotion of an FDA-approved pharmaceutical product.

385. Actavis marketed, promoted, and detailed Androderm for "off-label" use for the purpose of "label expansion," and detailed and promoted the product to

physicians, and advertised the product to consumers and patients, promoting the idea that a reduced testosterone level is synonymous with hypogonadism and that Androderm is approved and indicated for clinical use in treating reduced testosterone.

Defendants' Failure to Warn of the Risks and Dangers of TRT Products

386. Defendants' marketing strategy has been aggressively to market and sell their products by misleading potential users and their physicians about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of their products.

387. Defendants successfully marketed TRT products by undertaking "disease awareness" marketing campaigns. These campaigns sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to "Low T."

388. Defendants' advertising programs sought to create the image and belief by consumers that the use of TRT was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

389. Defendants promoted and marketed TRT to physicians as a lifestyle drug that could treat a variety of symptoms caused by the normal aging process in males, including: erectile dysfunction; loss of libido; loss of athleticism; loss of muscle mass; fatigue; and mood swings. Defendants overstated the benefits of testosterone as a treatment for lifestyle changes associated with the aging process despite the fact that the drug was never FDA approved for these uses.

390. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using TRT products. Defendants deceived potential TRT product users and their physicians by relaying positive information

through the press, including testimonials from retired professional athletes, and manipulating the definition of hypogonadism and statistics of its occurrence in men to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

391. Defendants concealed material relevant information from potential TRT users, and their physicians, and minimized user and prescriber concern regarding the safety of TRT, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users.

392. Testosterone regulates the expression of platelet TXA2 receptors in humans, which significantly increases platelet aggregation. It causes an increase in hematocrit and estradiol in adult males, resulting in thickened blood, the development of blood clots, and heart damage. These effects, if not monitored and controlled properly, can lead to life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries.

393. Use of exogenous testosterone can cause an increase in serum levels of estradiol, the primary female sex hormone, through the conversion of excess testosterone into estradiol. Increased serum levels of estradiol have been associated with the development of blood clots and with life threatening cardiac events, strokes and thromboembolic events, including but not limited to deep vein thrombosis, pulmonary embolism, transient ischemic attacks, ischemic stroke, and numerous types of cardiovascular injuries

394. At relevant times, the warnings Defendants gave in their commercials, online and print advertisements failed to mention any potential risk of cardiac event, stroke, pulmonary embolism or other dangerous side effects related to blood clotting and falsely represented that Defendants adequately tested TRT products for all likely

side effects. Defendants also failed to warn and instruct regarding the importance of adequate monitoring of hematocrit and estradiol levels.

395. At relevant times, the prescribing information and medication guides contained within the package materials of each of the Defendants' TRT products did not adequately warn against stroke, pulmonary embolism, transient ischemic attack, cardiovascular disease, myocardial infarction, coronary heart failure, or any thromboembolic event not related to polycythemia.

396. At relevant times, the medication guide contained within the package materials of each of the Defendants' TRT products instructed patients to tell their healthcare provider if they have any of the following before initiating use of a TRT product: (a) breast cancer; (b) prostate cancer; (c) urinary problems due to an enlarged prostate; (d) heart problems; (e) kidney or liver problems; (f) problems breathing while during sleep (sleep apnea); or (g) any other medical conditions.

397. However, the prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products failed to instruct patients to tell their healthcare provider if they have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant. The prescribing information also failed to instruct patients or physicians to be aware of the presence of comorbid conditions or pre-existing heart disease, which has been proven to double the risk in men under the age of 65 who use testosterone therapy.

398. Although the prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products did warn that the use of the product may result in increased red blood cell count, at relevant times it did not instruct physicians or patients that it can increase a red blood cell count to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart

disease, coronary heart failure, and myocardial infarction. The warning in regard to red blood cell count did not warn patients and their physicians that hematocrit levels can rise by as much as 10% above normal range, nor did it warn of the serious and life threatening risks that are associated with a red blood cell count that exceeds 50%, including the fact that individuals with a hematocrit greater than or equal to 51% have a doubling of the risk of stroke, new-onset heart failure, and coronary heart disease.

399. The prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products did instruct physicians to re-evaluate their patient's hematocrit 3 to 6 months after starting treatment, but at relevant times failed to warn patients and their physicians that the product can cause dangerous increases in hematocrit much more rapidly, and also failed to instruct physicians to monitor their patient's hematocrit more frequently.

400. The prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products failed at relevant times to state that testosterone replacement therapy should not be administered to men who have an underlying inherited trait which increases their risk of blood clotting, particularly the Factor V Leiden mutation, the Prothrombin gene mutation, high Factor VIII, high homocysteine, or the lupus anticoagulant because the increase in serum estradiol caused by the drug can interact with the underlying clotting trait to produce blood clots in the legs, the lungs, the eyes, the brain, and the bones. The materials also failed to instruct physicians to screen all patients for underlying clotting traits before prescribing testosterone replacement therapy.

401. Although the prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products warned that use of the product may result in risk of blood clots in the veins, at relevant times the warning was specifically limited to "blood clots in the legs" and only warned against blood clots in the legs that form as a result of increased red blood cell count

(polycythemia). There was no warning for blood clots in the veins other than "blood clots in the legs," nor was there any warning of blood clots resulting from causes other than polycythemia. Also, there were no warnings that blood clots in veins as a consequence of polycythemia could result in pulmonary embolism, or other injuries secondary to the formation of deep vein thrombosis in the legs or other parts of the body.

402. The prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products failed to warn that use of the product may result in elevated levels of estradiol. Defendants did not instruct physicians to monitor estradiol levels, nor did they provide any guidance to physicians or patients regarding the significant health risks associated with elevated levels of serum estradiol in men, including the fact that there was a two-fold excess risk of stroke for men who had serum estradiol levels in the top quintile versus those men whose estradiol levels were lower, and that estradiol blood levels greater than 34.1 pg/mL resulted in more than doubling of stroke incidence in men. There was also no warning that elevated serum estradiol levels resulting from use of the product can cause impairment of contractility of the heart.

403. The prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products did not adequately warn that use of the product may result in the formation of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction caused by elevated levels of estradiol.

404. At relevant times, the prescribing information and medication guide contained within the package materials of each of the Defendants' TRT products did not offer any warning of the very serious health risks for men over the age of 65 who use testosterone replacement therapy. There was no mention of the fact that there is a doubling of the risk of heart attacks in men over the age of 65 who use testosterone

replacement therapy, despite the fact that the data supporting this finding has been available for years. The absence of a warning failed to adequately advise and instruct patients and their physicians of the very serious health risks caused by the use of testosterone in this patient population.

405. Defendants' research into their products put them in a position to be aware of the risks and danger of the use of TRT products, in particular the risks of deep vein thrombosis, pulmonary embolism, stroke, infarction, coronary heart failure, cardiovascular disease, or myocardial infarction at the time they brought their products to market. This is particular true because the dangers of increased serum levels of estradiol have long been understood in the context of oral contraceptives and hormone replacement therapy for women. Defendants nonetheless failed to warn doctors and consumers of these dangers.

406. To the extent that any dangers of resulting from testosterone replacement therapy were not known at the time any of the products were brought to market, the Defendants, and each of them, were entitled, and required, to make unilateral changes to the labels for their products in order to warn physicians and consumers of dangers of which they became aware.

407. AbbVie failed adequately to warn physicians and consumers of the risks and dangers of AndroGel, as described above.

408. Lilly failed adequately to warn physicians and consumers of the risks and dangers of Axiron, as described above.

409. Endo failed adequately to warn physicians and consumers of the risks and dangers of Fortesta and Delatestryl, as described above.

410. Auxilium failed adequately to warn physicians and consumers of the risks and dangers of Testim, Testopel, and Striant, as described above.

411. Pfizer failed adequately to warn physicians and consumers of the risks and dangers of Depo-Testosterone, as described above.

412. Actavis failed adequately to warn physicians and consumers of the risks and dangers of Androderm, as described above.

413. In November of 2013, Rebecca Vigen, Colin I. O'Donnell, Anna E. Barón, Gary K. Grunwald, *et al*. published as article in the *Journal of the American Medical Association* entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" ("Vigen Paper").

414. The Vigen Paper concluded that: "Use of testosterone therapy in this cohort of veterans with significant medical comorbidities was associated with increased risk of mortality, MI, or ischemic stroke." In fact, testosterone therapy increased the risk of death, heart attack, and stroke by approximately 30%.

415. On January 29, 2014, William D. Finkle, Sander Greenland, Gregory K. Ridgeway John L. Adams, *et al*. published an article in PLOS ONE entitled *Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men* ("Finkle Paper").

416. The Finkle Paper demonstrated an increased risk of heart attack in men over age 65 years, and in men younger than 65 years with a prior history of heart disease.

417. Prior to the publication of the Vigen Paper and the Finkle Paper, Plaintiffs and their prescribing doctors did not know, and could not have known, of the undisclosed risks and dangers of exogenous testosterone therapy in men without hypogonadism.

418. On June 19, 2014, and in response to post-market reports of venous blood clots unrelated to polycythemia in testosterone users, the FDA announced that it was requiring manufacturers of testosterone to include a general warning in the drug labeling of all approved testosterone products about the risk of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

419. As a result of this mandate by the FDA, on June 21, 2014, the Defendants updated the prescribing information to provide the general warning required by FDA regarding DVT and PE, and also updated the medication guide to include the significant risk of PE as follows: "Blood clots in the legs *or lungs*. Signs and symptoms of a blood clot in your leg can include leg pain, swelling, or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain." (Emphasis in original.)

420. However, the prescribing information and the medication guide contained within the package materials of each of the Defendants' TRT products still lack any warning about the risks of elevated estradiol levels, the need to screen for underlying clotting traits, and they contains no warnings for strokes, or for cardiovascular injuries.

421. This warning fails to warn about blood clots that occur in locations other than the legs and lungs, i.e. the arms, spinal cord, heart, and other locations throughout the body or that injuries secondary to the formation of deep vein thrombosis or pulmonary embolism may occur.

422. As of February 2, 2015, prescribing information and medication guide contained within the package materials for each of the Defendants' TRT products fail to provide any warning to consumers or physicians against:

a. Avascular Necrosis;

b. Cardiovascular Disease;

c. Cerebrovascular Accident (Stroke);

d. Coronary Heart Failure;

e. Myocardial Infarction (Heart Attack); or

f. Transient ischemic attack (TIA).

423. One of the mechanisms by which TRT products can cause injuries is through the elevation of an individual's red blood cell count, hematocrit and hemoglobin levels.

424. The product labeling for each of Defendants' TRT products fails to adequately warn that testosterone increases red blood cell production and that testosterone can increase red blood cell counts to the point that it more than doubles the risk for stroke, pulmonary embolism, ischemic heart disease, coronary heart failure and myocardial infarction.

425. Defendants fail to instruct physicians or patients that:

a. Dangerous increases in hematocrit can happen rapidly;

b. There are serious and life threatening risks, including stroke, new-onset heart failure, and coronary heart disease, that are associated with a red blood cell count that exceeds 50%; and

c. Hematocrit levels need to be monitored frequently.

426. Defendants failed to warn that use of their TRT products may result in elevated levels of Thromboxane A2 and failed to instruct physicians to monitor Thromboxane A2 levels. Defendants failed to provide any guidance to physicians and patients regarding the significant health risks associated with elevated levels of Thromboxane A2 in men.

427. Defendants' marketing and promotion of the product to patients and physicians overstated its benefits by creating the impression that it was a safe and effective treatment for a variety of aging-related conditions and symptoms, for which it was not FDA approved. This is misleading and fails to adequately warn physicians and patients about the numerous, life-threatening health risks associated with use of the drug.

428. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for TRT products. If Plaintiffs and their physicians had known the risks and dangers associated with TRT products, the physicians would not have prescribed nor would Plaintiffs would have taken TRT products and consequently would not have been subject to its

serious side effects; and/or, Plaintiffs' physicians would have adequately monitored Plaintiffs' hematocrit and estradiol levels, and, as a result, Plaintiffs' injuries would have not otherwise have occurred.

429. On March 3, 2015, the FDA issued a Safety Announcement, cautioning that "prescription testosterone products are approved only for men who have low testosterone levels caused by certain medical conditions" and specifically noting that "[t]he benefit and safety of these medications have not been established for the treatment of low testosterone levels due to aging, even if a man's symptoms seem related to low testosterone." The FDA also announced that it was "requiring labeling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use."

Defendants' Fraud on the FDA

430. Defendants intentionally withheld from or misrepresented to the U.S. Food and Drug Administration ("FDA") information concerning its testosterone-containing prescription drug products that were required to be submitted under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and/or 378 to 395.

431. As more fully set forth below in the paragraphs below, had Defendants not withheld or misrepresented this information to the FDA, the subject testosterone-containing prescription drugs would not have been approved by the FDA.

432. Title 21 U.S.C. § 331 provides: "The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any … drug … that is adulterated or misbranded."

433. Title 21 U.S.C. § 352 provides: "A drug or device shall be deemed to be misbranded - (a) False or misleading label…If its labeling is false or misleading in any particular."

434. More specifically, 21 U.S.C. 321 (n), provides:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

435. The label submitted to the FDA by Defendants in their New Drug Application ("NDA") of their TRT prescription drug products listed the intended indications for clinical use of the drug as:

> Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
>
> Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

436. Defendants' product labelling does not list as indications for clinical use those industry-fabricated "conditions" for which Defendants contemplated that the drugs would actually be marketed, promoted, detailed, and prescribed in a large segment of the male population: the treatment of "Low T" or age-related declines in testosterone levels or age related symptoms or "andropause," or "geriatric hypogonadism," or the "male climacteric."

437. At the time of FDA approval, Defendants' testosterone-containing prescription drug products were misbranded.

438. Defendants' testosterone-containing prescription drug products were

misbranded because Defendants intentionally misrepresented information to the FDA concerning Defendants' actual and contemplated use of their testosterone containing products for the treatment of "Low T" or age-related declines in testosterone levels or age related symptoms or "andropause," or "geriatric hypogonadism," or the "male climacteric."

439. Defendants' testosterone-containing prescription drug products were misbranded because Defendants intentionally withheld information from the FDA concerning Defendants' actual and contemplated use of their testosterone containing products for the treatment of "Low T" or age-related declines in testosterone levels or age related symptoms or "andropause," or "geriatric hypogonadism," or the "male climacteric."

440. Had these aforementioned contemplated indications for clinical use ("Low T" or age-related declines in testosterone levels or age related symptoms or "andropause," or "geriatric hypogonadism," or the "male climacteric"), for which there is no data to support either the safety or efficacy for such use, been submitted to and not misrepresented to the FDA, as they should have been in the New Drug Application ("NDA") approval process, the FDA would not have approved these products for clinical use.

441. Had Defendants not intentionally misrepresented to the FDA that their testosterone-containing prescription products were to be used for the treatment of primary and hypogonaotrophic hypogonadism, and instead stated the actual aforementioned indications for clinical use ("Low T" or age-related declines in testosterone levels or age related symptoms or "andropause," or "geriatric hypogonadism," or the "male climacteric") contemplated by Defendants for the marketing, promotion, detailing, and advertising of these products, the FDA would not have approved these products for clinical use.

442. Had Defendants not intentionally withheld material information from the

FDA concerning the actual aforementioned indications for clinical use ((“Low T” or age-related declines in testosterone levels or age related symptoms or “andropause,” or “geriatric hypogonadism,” or the “male climacteric”) contemplated by Defendants for the marketing, promotion, detailing, and advertising of these products, the FDA would not have approved these products for clinical use.

443. Defendants obtained NDA approval from the FDA by misrepresentation and deceit with regard to this agency, and misrepresented to the FDA, and withheld from the FDA, material information concerning the clinical indications for use of their testosterone-containing drug products. Had this materially false information been presented to the FDA, Defendants' products would not have been approved.

444. Defendants intentionally misrepresented to the FDA that the clinical use of their testosterone-containing products were for the treatment of “classical hypogonadism,” namely those indications listed on the label. In fact, Defendants' contemplated indications for clinical use, marketing, promotional, and detailing schemes belied the documentation set forth for the FDA in the NDA documentation.

445. In 2004, Dr. Daniel Shames of the FDA stated in the prestigious medical publication, the *New England Journal of Medicine*:

> More than 50 years ago, physicians began treating the “male climacteric” with testosterone. Since then, no standardized definition of this condition has been developed, no metric defining a therapeutic effect has been created, no randomized controlled studies have been conducted to support the widespread use of testosterone in men for this condition, and the adverse-event profile of the drug in this population has not been studied adequately. *The Food and Drug Administration (FDA) has not approved testosterone for this condition*.

N. ENGL J MED 2004;c350:2004-2006) (emphasis added).

446. Dr. Shames is the former Director of the Division of Bone Reproductive and Urologic Drug Products ("DRUDP") at the FDA from 2001 to 2006, and supervised the Scientific, Regulatory and Administrative functions of the Division which reviewed

therapeutic products for clinical areas such as contraception, infertility, obstetrics, menopause, urinary incontinence, over-active bladder, male and female sexual dysfunction, benign prostatic hypertrophy, testosterone replacement, osteoporosis, and hormonal therapy for prostatic cancer.

447. Dr. Shames was previously Deputy Director of DRUP from 2000 to 2001; Team Leader in Urology and Endocrine at DRUP from 1998 to 2000; and a Medical Officer in Urology at DRUP from 1996-1998.

448. Dr. Shames's statement in the *New England Journal of Medicine* shows that the FDA would not have approved TRT products for the off-label use for which Defendants intended to market them.

449. Defendants obtained approval of TRT drug products under intentionally false and misleading circumstances by withholding material information concerning the true and correct contemplated use for their prescription testosterone-containing products and by misrepresenting to the FDA that the products would be used to treat primary and hypogonadotrophic hypogonadism.

450. The FDA did not approve Defendants' prescription testosterone-containing drugs from the treatment of "Low T" or age-related declines in testosterone levels or age related symptoms or "andropause," or "geriatric hypogonadism," or the "male climacteric" as clearly inferred from Dr. Shames' statement in 2004, and would not have approved these products for those purposes because "there was no standardized definition of this condition … no metric defining a therapeutic effect … no randomized controlled studies have been conducted to support the widespread use of testosterone in men for this condition, and the adverse-event profile of the drug in this population has not been studied adequately."

451. By intentionally misrepresenting the proposed clinical indications for their prescription testosterone-containing products' use, Defendants were able to obtain FDA approval for prescription drugs that the FDA would not have otherwise approved.

452. By intentionally withholding information concerning the proposed clinical indications for their prescription testosterone-containing products' use, Defendants were able to obtain FDA approval for a prescription drug that the FDA would not have otherwise approved.

453. Defendants' prescription testosterone-containing products were misbranded at the time of FDA approval because Defendants intentionally withheld and misrepresented information from the FDA in such way as to obtain FDA approval for misbranded drug products.

454. The FDA would not have otherwise approved Defendants' misbranded prescription testosterone-containing products but for the fact that Defendants intentionally withheld and misrepresented information from the FDA in such way as to obtain FDA approval for their misbranded drug products, because it is prohibited to introduce or deliver "for introduction into interstate commerce … any … drug … that is adulterated or misbranded." 21 U.S.C. § 331.

455. Drs. L.M. Schwartz, and S. Woloshin have stated in an article published in the prestigious *Journal of the American Medical Association* entitled "Low T as a Template: How to Sell as Disease":

> Whether the campaign is motivated by a sincere desire to help men or simply by greed, we should recognize it for what it is: a *mass, uncontrolled experiment* that invites men to expose themselves to the harms of a treatment unlikely to fix problems that may be wholly unrelated to testosterone levels.
>
> We agree with Braun that there is a strong analogy between the marketing of testosterone therapy for men and estrogen therapy for menopausal women. Ignoring the lessons of estrogen therapy is scandalous.

JAMA 2013; 173(15):1460-1462 (emphasis added).

456. The FDA would not have permitted Defendants to perform a "mass, uncontrolled experiment" via the FDA approval process of their prescription

testosterone-containing drug products had Defendants not misrepresented to the FDA the actual clinical indications for which Defendants planned to market, promote, and detail the drug products.

457. The FDA would not have approved these drug products which were designed, manufactured, marketed, promoted, detailed, and ultimately prescribed for the treatment of an industry-created, pseudo-disease by way of "a mass, uncontrolled experiment" unfettered by any of the regulatory safeguards and oversights which apply to human research and the protection of human subjects. *See* 45 C.F.R. 46 (policies for the protection of human subjects and the oversight of research); *see also* The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (April 18, 1979); World Medical Association (WMA), *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* (adopted 1964-last revised 2013).

458. Defendants materially and intentionally misrepresented to the FDA the contemplated and actual indications for use for their testosterone-containing prescription products, and thereby garnered FDA approval for prescription drugs that the FDA would have not approved otherwise but for Defendants' intentional material misrepresentations.

459. Defendants intentionally and materially misrepresented to the FDA that they were seeking FDA approval of their testosterone-containing drug products for the treatment of "classical hypogonadism," when, in fact, they were seeking approval of testosterone-containing products for the treatment of "Low T."

460. "Low T" is not a bona fide disease nor a bona fide clinical syndrome, and the FDA would not have approved Defendants' testosterone-containing products to treat "Low T." The FDA would not have approved prescription drug products to treat a disease crafted from the imagination of Defendants for the purpose of creating an

unindicated use of a drug product.

461. Defendants intentionally provided the FDA with materially false information which misrepresented Defendants' actual and true intended clinical use of their testosterone-containing drug products. This was purposefully and intentionally undertaken to expand the market space for prescription testosterone-containing drug products by way of a "mass, uncontrolled experiment."

462. The FDA would not have approved Defendants' testosterone-containing prescription drugs, which were marketed, promoted, and detailed for the purpose of treating "Low T" by way of "a mass, uncontrolled experiment," because such an experiment would require Institutional Review Board approval, protocol oversight, and informed consent of the involved subjects. *See* 45 C.F.R. 46 (policies for the protection of human subjects and the oversight of research).

463. The FDA's Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee ("Ad. Comm.") was convened on September 17, 2014. This meeting was convened by the FDA to discuss, *inter alia*, "the appropriate indicated population for testosterone replacement therapy."

464. The Ad. Comm. concluded in the approved Summary Minutes published on October 5, 2014 by the FDA Center for Drug Evaluation and Research:

> The joint committees agreed that the use of testosterone replacement products in men with inherited or acquired loss of testosterone production in conjunction with a recognized disease condition ("classical hypogonadism") was supported by data. There was general consensus that the current paradigm for drug development is not capable of generating data in support of testosterone replacement therapy for "age-related hypogonadism." Committee members agreed that the current information supports an indication only for classical hypogonadism and not for age-related hypogonadism.

(Emphasis added)

465. Defendants intentionally misrepresented to the FDA that it was seeking approval of prescription testosterone drug products for the clinical use of treating "classical hypogonadism," when, in fact, Defendants' actual intention was to market, promote distribute, and sell the drugs for the treatment of "Low T."

Fraudulent Concealment and Discovery Rule

466. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

467. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants. Plaintiffs have been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part.

468. Plaintiffs could not reasonably have discovered the injury and its cause until shortly before the initiation of these actions.

469. Defendants were under a continuing duty to disclose the true character, quality and nature of the TRT products identified herein to the Plaintiffs. Because of their concealment of the true character, quality, and nature of the TRT products to Plaintiffs, Defendants are estopped from relying on any statues of limitations defense.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Strict Liability – Design Defect

470. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

471. Defendants participated in the manufacture, sale and marketing of testosterone drugs that were FDA approved to treat a specific medical condition called hypogonadism, which is defined as a condition in which a male produces no or very low testosterone in conjunction with an associated medical condition, such as failure of the testicles to produce testosterone for reasons such as genetic problems or

chemotherapy.

472. Defendants manufactured, sold and promoted these drugs to treat a non-existent medical condition that they called "Low T," which was a name they created for the constellation of symptoms experienced by men as a result of the normal aging process. In essence, Defendants marketed and sold TRT as lifestyle drugs meant to make men feel younger and increase libido.

473. Defendants manufactured, sold, and promoted these drugs which contained a defective condition because the design was defective and unsafe in that they caused serious injuries and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

474. The design of each of AndroGel, Axiron, Fortesta, Delatestryl, Testim, Testopel, Striant, Depo-Testosterone, and Androderm was defective and unsafe in that each caused serious injuries and death as the result of the formation of blood clots and adverse cardiovascular events, including but not limited to deep vein thrombosis, pulmonary embolism, stroke, ischemic injuries, infarctions, coronary heart failure, and cardiovascular disease.

475. This design defect made these drugs unreasonably dangerous, yet Defendants knowingly introduced the drugs into the market.

476. The drugs as manufactured by Defendants remained unchanged and were in the same condition at the time of the injuries hereafter alleged.

477. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drugs, Plaintiffs sustained permanent injury.

478. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general

public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspected public. Defendants' reckless conduct warrants an award of punitive damages.

479. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SECOND CLAIM FOR RELIEF

Strict Liability – Failure to Warn

480. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

481. Defendants researched, developed, designed, tested, manufactured, inspected labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the TRT products, in the course of same, directly advertised or marketed the products to the FDA, health care professionals, and consumers, including the Plaintiffs, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the TRT products.

482. The TRT products manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

483. AbbVie, Lilly, Endo, Auxilium, GSK, Pfizer, and Actavis all failed adequately to warn consumers and/or their health care providers that TRT could cause heart attacks, strokes, pulmonary embolism, cardiovascular events and blood clots.

484. AbbVie, Lilly, Endo, Auxilium, GSK, Pfizer, and Actavis all failed to adequately warn consumers and/or their health care providers that while a patient was taking TRT it was necessary to frequently monitor hematocrit and estradiol levels to

prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots.

485. Each of the TRT products manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of TRT, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the products, knowing the products could cause serious injury.

486. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

487. As a direct and proximate result of Plaintiffs' reasonably anticipated use of TRT as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of commerce by Defendants, Plaintiffs suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

488. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspected public. Defendants' reckless conduct warrants an award of punitive damages.

489. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory and punitive damages, in amounts to be proved at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRD CLAIM FOR RELIEF

Negligence

490. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

491. At all relevant times, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of TRT products.

492. Defendants had a duty to exercise reasonable care in the advertising and sale of the TRT products, including a duty to warn Plaintiffs and other consumers of the dangers associated with the TRT products that were known or should have been known to Defendants at the time of the sale of the TRT products to the Plaintiffs.

493. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of TRT to cause, or increase the harm of among other severe injuries, myocardial infarction, cerebrovascular accident, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiovascular death.

494. Defendants had a duty of care when they: (a) provided comprehensive medical information to consumers and patients concerning "Low T" as a medical diagnostic entity; (b) educated and informed consumers and patients about "Low T"; and (c) provided consumers and patients with the means for self-diagnostic screening and in-home testing for "Low T."

495. Defendants had a duty to disclose to physicians and healthcare providers the causal relationship or association of TRT products to heart attack, stroke, deep vein thrombosis and its sequelae, pulmonary embolism, and sudden cardiac death.

496. Defendants' duty of care owed to consumers and patients included providing accurate, true, and correct information concerning:

a. Hypogonadism and its diagnostic criteria;

b. The FDA-approved indications for the clinical use of TRT products;

c. The clinical safety and effectiveness profiles of TRT; and

d. Appropriate, complete, and accurate warnings concerning the adverse effects of TRT, including heart attack, stroke, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

497. At all times herein mentioned, Defendants breached their duty of care by negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use and selling TRT, and failing to adequately test and warn of the risks and dangers of TRT as described herein.

498. Defendants negligently and carelessly disregarded the applicable regulations and industry standards regarding the prohibition against off-label marketing, misbranding and label expansion. As a result millions of men, including Plaintiffs, were prescribed TRT unnecessarily, and were therefore needlessly exposed to serious health risks for which there were no or inadequate warnings.

499. At all times material hereto, Defendants sought to mislead and misinform physicians concerning the FDA-approved uses for TRT, including Plaintiffs' prescribing physicians. Specifically, the FDA had not approved TRT for the treatment of “Low T.”

500. At all times material hereto, Defendants recklessly, intentionally, and knowingly detailed and promoted TRT with the intent that men be prescribed testosterone therapy by physicians for "off-label" clinical indications.

501. Despite the fact that Defendants knew or should have known that TRT caused unreasonable, dangerous side effects, Defendants continued to market TRT to consumers including Plaintiffs, when there were safer alternative methods and/or no need to treat conditions such as loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions that TRT marketing materials claim are caused

by "Low T."

502. At all times material hereto, Defendants misbranded TRT products on an on-going and continuous basis, and failed to warn physicians and patients that TRT was not approved for the treatment of "Low T" or age-related declines in testosterone or age-related symptoms in men.

503. Defendants failed to disclose to physicians, consumers, and patients the known cardiovascular and cerebrovascular risks causally associated with TRT use.

504. Defendants failed to conduct adequate post-marketing surveillance.

505. As marketed, detailed, and promoted to physicians, including Plaintiffs' prescribing physicians, Defendants failed to warn that TRT caused, or increased the risk of harm of, cardiovascular and cerebrovascular injuries, including myocardial infarction and cerebrovascular accident, pulmonary embolism, deep vein thrombosis and its sequelae, and sudden cardiac death.

506. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injuries as a result of Defendants' failure to exercise ordinary care as described above.

507. Defendants' negligence was a proximate cause of the Plaintiffs' injuries, harm and economic losses which Plaintiffs suffered, and will continue to suffer, as described and prayed for herein.

508. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspected public. Defendants' reckless conduct warrants an award of punitive damages.

509. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with

interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTH CLAIM FOR RELIEF

Negligent Misrepresentation

510. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

511. From the time TRT products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety and efficacy of TRT products. Defendants made misrepresentations to Plaintiffs, Plaintiffs' physicians and the general public, including but not limited to the misrepresentation that "Low T" was an actual disease/medical condition for which medical treatment was indicated, and that TRT products were safe, fit, effective, and FDA approved for human consumption to treat "Low T." At all relevant times, Defendants conducted sales and marketing campaigns to promote the sale of TRT products and willfully deceived Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of the TRT products.

512. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the drugs they marketed, distributed and sold.

513. Defendants made the foregoing representations without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

514. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety risks associated

with TRT products that their representations regarding TRT products were false, and that they had a duty to disclose the dangers associated with the drugs.

515. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiffs, and the medical community to act in reliance by prescribing, purchasing and using TRT products.

516. The representations by the Defendants were in fact false, in that TRT products are not safe, fit and effective for human consumption, using TRT products are hazardous to health, and TRT has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs.

517. Plaintiffs and the medical community justifiably relied on Defendants' misrepresentations and nondisclosures to their detriment. Specifically, Plaintiffs relied on representations that "Low T" was an actual disease that required medical treatment and use of prescription TRT, that TRT products were FDA approved to treat a condition called "Low T," and that Defendants' testosterone drugs were a safe and effective treatment for their "Low T."

518. In reliance of the misrepresentations by the Defendants, Plaintiffs were induced to purchase and use TRT products. If Plaintiffs had known of the true facts and the facts concealed by Defendants, Plaintiffs would not have used TRT products. The reliance of Plaintiffs upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

519. As a direct and proximate result of the foregoing negligent misrepresentations by Defendants, Plaintiffs suffered injuries and damages as alleged herein.

520. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general

public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspected public. Defendants' reckless conduct warrants an award of punitive damages.

521. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FIFTH CLAIM FOR RELIEF

Breach of Implied Warranty of Merchantability

522. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

523. Prior to the time that the aforementioned products were used by Plaintiffs, Defendants impliedly warranted to Plaintiffs and Plaintiffs' agents and physicians that TRT products were of merchantable quality and safe and fit for the use for which they were intended.

524. Specifically, Defendants warranted to Plaintiffs that their products were intended to treat a condition called "Low T" and that they were safe and fit for that use, but Defendants failed to disclose that "Low T" is not a recognized medical condition and that TRT products were not FDA approved to treat any such condition.

525. TRT products were not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the products when used in the customary, usual and reasonably foreseeable manner. Nor were TRT products minimally safe for their expected purpose.

526. TRT products were neither safe for their intended use nor of merchantable quality, as warranted by Defendants, in that TRT has dangerous propensities when used as intended and will cause severe injuries to users.

527. At all relevant times, Plaintiffs used TRT products for the purpose and in the manner intended by Defendants.

528. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

529. The breach of warranty was a substantial factor in bringing about Plaintiffs' injuries.

530. As a direct and proximate result of the aforementioned breach of implied warranties by Defendants, Plaintiffs suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial

531. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory damages in an amount to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SIXTH CLAIM FOR RELIEF

Breach of Express Warranty

532. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

533. At all times mentioned, Defendants expressly represented and warranted to Plaintiffs and Plaintiffs' agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that TRT products were FDA approved to treat a condition called "Low T", and that they were safe, effective, fit and proper for their intended use. Plaintiffs purchased TRT products relying upon these warranties.

534. Defendants advertised, labeled, marketed and promoted TRT products, representing the quality to health care professionals, the FDA, Plaintiffs, and the public in such a way as to induce their purchase or use, thereby making an express warranty

that TRT products would conform to the representations. More specifically, Defendants represented that TRT products were safe and effective, that they were safe and effective for use by individuals such as Plaintiffs, and/or that they were safe and effective to treat Plaintiffs' conditions.

535. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

536. In utilizing TRT products, Plaintiffs relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that there is no disease or medical condition called "Low T" that is recognized by any medical community, peer-reviewed journal, or learned treatise, and that TRT products are unsafe and unfit for their purported intended uses.

537. TRT products did not conform to the representations made by Defendants in that TRT products were not safe and effective for use by individuals, such as Plaintiffs, and/or was not safe and effective to treat individuals, such as Plaintiffs.

538. At all relevant times, Plaintiffs used TRT products for the purpose and in the manner intended by Defendants.

539. Plaintiffs and Plaintiffs' physicians, by the use of reasonable care, could not have discovered the breached warranty and realized their danger.

540. The breach of the warranty was a substantial factor in bringing about Plaintiffs' injuries.

541. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of TRT products, Plaintiffs were prescribed and used TRT products and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to cost of medical care, rehabilitation, lost

income, and pain and suffering for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

542. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory damages in an amount to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

SEVENTH CLAIM FOR RELIEF

Fraud

543. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

544. Through a sophisticated and well-orchestrated marketing campaign, Defendants set out to invent a fictitious disease/medical condition that they called "Low T," and then purposely deceived Plaintiffs and their physicians into believing that this was a real disease/medical condition and that Plaintiffs suffered from it. Defendants did this through marketing a set of generic and common conditions in middle-aged men, and representing that these conditions were "symptoms" of "Low T." Those commonly occurring conditions were listed in the "Is It Low T Quiz," and included:

a. Being tired after dinner
b. Diminished ability to play sports
c. Lack of energy
d. Being sad
e. Being grumpy
f. Decreased libido

545. Each of these purported "symptoms" of "Low T" are normal and common conditions for men over the age of 40 and especially common in men over the age of 50.

546. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed TRT products, and up to the

present, knew that their products could cause an increase in hematocrit in patients to a level that more than doubles their risk for stroke, heart attack, and clot formation that could result in pulmonary embolism, and as result of published, peer-reviewed medical literature knew that the use of their products could result in a dramatic increase in serum estradiol levels, yet Defendants willfully deceived Plaintiffs by concealing from them, Plaintiffs' physicians and the general public, the true facts concerning TRT products, which Defendants had a duty to disclose.

547. At all times herein mentioned, Defendants conducted sales and marketing campaigns to promote the sale of TRT products and willfully deceived Plaintiffs, Plaintiffs' physicians and the general public as to the benefits, health risks and consequences of using TRT products. Defendants knew of the foregoing, that TRT products are not safe, fit and effective for human consumption, that using TRT products are hazardous to health, and that TRT products have a serious propensity to cause serious injuries to their users, including but not limited to the injuries Plaintiffs suffered.

548. Defendants knowingly, falsely, deceptively, and inaccurately designated the physiologic decrease in men's testosterone levels and the age-related symptoms men experience with aging as a form of acquired hypogonadism with the intent: (a) to deceive physicians into prescribing TRT products for "off-label" indications for clinical use; (b) to engage in "label expansion" of the TRT products; and (c) to drive increasing consumer and patient demand for TRT prescriptions.

549. Defendants knowingly, falsely, deceptively, and inaccurately misstated the clinical effectiveness profile of TRT products to physicians, to include statements concerning the effectiveness of treatment of the age-related signs and symptoms included on the "Interactive ADAM Questionnaire." There was no double-blind, placebo-controlled, randomized, sufficiently powered, and independent study or clinical investigation or clinical evidence to support this use of TRT products, and no

approval by the FDA to warrant promotion of these indications for clinical use.

550. Defendants knowingly, falsely, deceptively, and inaccurately designated and represented that the physiologic decline in men's testosterone levels and the age-related symptoms men experience with advancing age, as a form of "acquired hypogonadism" with the intent to confuse and deceive consumers and patients, and to foster the belief by consumers and patients, including Plaintiffs, that they harbored a "disease" or pathologic medical condition that was appropriately treated with TRT products.

551. Defendants concealed and suppressed the true facts concerning TRT products, and the actual disease for which they have been FDA approved to treat (hypogonadism), with the intent to defraud Plaintiffs, in that Defendants knew that Plaintiffs' physicians would not prescribe TRT products, and Plaintiffs would not have used TRT products, if they were aware of the true facts concerning their dangers.

552. Defendants undertook to inform and educate consumers about the diagnostic hallmarks of "Low T," and engaged in and encouraged mass consumer screening for "Low T" via patient-directed questionnaires, quizzes, and information, as part of mass marketing efforts to encourage patients to seek treatment for "Low T," while having actual knowledge that TRT products were not indicated for the treatment of "Low T," nor were they proven to be clinically safe and effective for treating "Low T" or age-related declines in testosterone levels or age-related symptoms in men.

553. Defendants knew, understood, and intended that consumers would rely upon the comprehensive medical information that they provided to consumers and patients through their multi-platform marketing, promotional, educational, and awareness campaigns concerning the TRT products and their indications for clinical use; and further knew that consumers and patients would make treatment choices and exercise treatment options about their use of TRT products in reliance upon this information.

554. Defendants deceived physicians by explicitly or implicitly claiming that the treatment of "Low T" was an FDA-approved clinical indication for use of TRT products, when in fact it was an "off-label" indication for clinical use.

555. Consumers, including Plaintiffs, required, and should have been provided with, truthful, accurate, and correct information concerning the FDA-approved indications for the clinical use for TRT products and the clinical safety and effectiveness profiles for TRT, including information concerning the "off-label" use of the TRT products.

556. Plaintiffs relied on the fraudulent and deceptive representations made by the Defendant to their detriment. Specifically, Plaintiffs relied on representations that "Low T" was an actual disease that required medical treatment and use of prescription testosterone, that TRT was FDA approved to treat a condition called "Low T," and that Defendants' testosterone drugs were a safe and effective treatment for their "Low T."

557. Plaintiffs would not have sought or continued treatment for "Low T" or administered TRT had they been provided with adequate, true, accurate, and correct information by Defendants about the risks of cardiovascular events and cerebrovascular accident causally associated with the use of TRT products, and the fact that "Low T" was not an FDA-approved indication for clinical use of TRT.

558. Plaintiffs would not have sought or continued treatment for "Low T," or administered TRT products, had they been provided with adequate, true, accurate, and correct information by Defendants, including information that there were no proven clinical profiles of safety or effectiveness for the use of TRT products to treat "Low T."

559. During the detailing, marketing, and promotion to physicians, neither Defendants nor the co-promoters who were detailing TRT products on behalf of Defendants warned physicians, including Plaintiffs' prescribing physicians, that TRT caused or increased the risk of harm of cerebrovascular accident and neurologic injuries.

560. Defendants, through their national direct-to-consumer multi-platform outreach campaigns and medical educational formats, materials, and programs, undertook to inform the consuming public and patients, including Plaintiffs, about a "disease" Defendants denominated and characterized as "Low T."

561. These materials did reach Plaintiffs, and they relied upon these materials in reaching their decision to purchase, use, and continue the use of TRT products throughout their course of testosterone therapy.

562. Plaintiffs would not have administered TRT to himself had the educational and informational materials made available to them by Defendants, and upon which they relied to their detriment, informed them about the risks of cardiovascular events and cerebrovascular accident with product use.

563. As a direct and proximate result of Defendants' fraudulent and deceitful conduct, Plaintiffs suffered injuries and damages as alleged herein.

564. Defendants' conduct, as described above, was reckless. Defendants risk the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspected public. Defendants' reckless conduct warrants an award of punitive damages.

565. By reason of the foregoing, Defendants are liable to Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

EIGHTH CLAIM FOR RELIEF

Redhibition

566. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

567. TRT products contain a vice or defect which renders them useless or their

use so inconvenient that buyers would not have used TRT products.

568. Defendants sold and promoted TRT products, which Defendants placed into the stream of commerce. The seller warrants the buyer against redhibitory defects, or vices, in the thing sold. The TRT products sold and promoted by Defendants possesses a redhibitory defect because they were not manufactured and marketed in accordance with industry standards and/or are unreasonably dangerous, as described above, which renders TRT products useless or so inconvenient that it must be presumed that buyers would not have used TRT products had they known of the defects. Plaintiffs are entitled to obtain a rescission of the sale of the TRT products.

569. TRT products alternatively possess a redhibitory defect because they were not manufactured and marketed in accordance with industry standards and/or are unreasonably dangerous, as described above, which diminishes the value of TRT products so that it must be presumed that buyers would still have purchased them but for a lesser price. In this instance, Plaintiffs are entitled to a reduction of the purchase price.

570. Defendants are liable as bad faith sellers for selling defective products with knowledge of the defects and are thus liable to Plaintiffs for the price of the TRT products, with interest from the purchase date, as well as reasonable expenses occasioned by the sale of the TRT products, and attorneys' fees. As the manufacturers of the TRT products, Defendants are deemed to know that TRT products possessed a redhibitory defect.

571. By reason of the foregoing, Defendants are liable to Plaintiffs for whom this claim is applicable for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

NINTH CLAIM FOR RELIEF

Consumer Protection

572. Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

573. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below when they failed to adequately warn consumers and the medical community of the safety risks associated with TRT products. As a direct result of Defendants' deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

574. There are no "party plaintiffs" to this Master Complaint. However, to the extent an individual by his or her attorney enters a pleading by way of adoption then it is alleged that Plaintiff is a resident of the state set forth in the pleading by way of adoption and wherever a given plaintiff resides, then that state's consumer protection law violation will be adopted by reference.

575. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. §45.50.471.

576. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. Ann. §§44-1521 et seq.

577. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code Ann. §§4-8-101 et seq.

578. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §§1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq.

579. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. §§6-1-105

et seq.

580. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. Ann. §§42-11Oa et seq.

581. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Del. Code Ann. tit. 6 §§2511 et seq. and 2531 et seq.

582. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of D.C. Code Ann. §§28-3901 et seq.

583. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Florida Stat. Ann. §501.201.

584. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code Ann. §§10-1-372 and 10-1-420.

585. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §§480-1 et seq.

586. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code §§48-601 et seq.

587. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 Ill. Comp. Stat. 505/1 et seq.

588. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. 24-5-0.5-3.

589. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code §714.16.

590. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. Ann. §§50-623 et seq.

591. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. Ann. §367.170.

592. Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Me. Rev. Sta. Ann. tit. 5, §§205-A et seq.

593. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Code Ann., Com. Law §§13-301 et seq.

594. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Ge. Laws ch. 93A, §§I et seq.

595. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. §§445.901 et seq.

596. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mo. Ann. Stat. §§407.010 et seq.

597. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Aim. §§30-14-101 et seq.

598. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §§59-1601 et seq.

599. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. §§598.0903 et seq.

600. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. Ann. §§358-A:1 et seq.

601. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. §§56:8-1 et seq.

602. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §§57-12-1 et seq.

603. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§349 et seq. and 350-e et seq.

604. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §§75-1 et seq.

605. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§51-12-01 et seq. and 51- 15-01 et seq.

606. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Code Ann. §§1345.01 et seq.

607. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or have made false representation in violation of Okla. Stat. Ann. tit. 15, §§751 et seq.

608. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. §§646.605 et seq.

609. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Cons. Stat. §§201-1 et seq.

610. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws §§6-13.1-1 et seq.

611. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Ann. §§39-5-10 et seq.

612. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws §§37-24-1 et seq.

613. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code Ann. §47-18-109(a)(l).

614. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code Ann. §§17.41 et seq.

615. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. §§13-11-1 et seq.

616. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §§2453 et seq.

617. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code Ann. §§59.1-196 et seq.

618. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wash. Rev. Code Ann. §§19.86.010 et seq.

619. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W.Va. Code 46A-6-101 et seq.

620. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. Ann. §100.18.

621. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. Ann. §§40-12-101 et seq.

622. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of. Minn. State. §325D.44(13) et. seq. and Minn. Stat. §325F.67

623. The actions and failure to act of Defendants, including the false and misleading representations and omissions of material facts regarding the safety and potential risks of TRT products and the above described course of fraudulent conduct and fraudulent concealment constitute acts, uses or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations, and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression or omission of material facts in connection with the sale of merchandise of Defendants in violation of the consumer protection statutes listed above.

624. The medical community relied upon Defendants' misrepresentations and omissions in determining whether to utilize and/or prescribe TRT.

625. By reason of the unlawful acts engaged in by Defendants, Plaintiffs have suffered ascertainable loss and damages.

626. As a direct and proximate result of Defendants' conduct, Plaintiffs suffered and will continue to suffer personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

627. By reason of the foregoing, Defendants are liable to Plaintiffs under applicable law for compensatory and punitive damages to the extent available, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all

such other relief as the Court deems proper.

TENTH CLAIM FOR RELIEF

Unjust Enrichment

628. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

629. As an intended and expected result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from payments Plaintiffs made for TRT products.

630. In exchange for the payments made for TRT products, and at the time payments were made, Plaintiffs expected that TRT products were safe and medically effective treatment for the condition, illness, disorder or symptom for which they were prescribed.

631. Defendants have voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiffs paid for TRT products when they otherwise would not have done so. The failure of Defendants to provide Plaintiffs with the remuneration expected enriched Defendants unjustly.

632. Plaintiffs are entitled to equity to seek restitution of Defendants' wrongful profits, revenues, and benefits to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

ELEVENTH CLAIM FOR RELIEF

Wrongful Death

633. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

634. Decedent Plaintiffs died as a result of the defects in Defendants' TRT products and are survived by various family members, named and unnamed.

635. The representatives/administrators of Decedent Plaintiffs' estate bring

this claim on behalf of the Decedent Plaintiffs' lawful heirs.

636. Defendants' wrongful conduct has proximately cause Decedent Plaintiffs' heirs to suffer the loss of Decedents' companionship, services, society, marital association, love, consortium and all other damages allowed under state statutes and laws.

637. Decedent Plaintiffs' estate representative brings this claim on behalf of Decedent Plaintiffs' lawful heirs for these damages and for all pecuniary losses sustained by the heirs.

638. Decedent Plaintiffs' estate representative further pleads all wrongful death damages allowed by statue in the state or states in which the causes of action accrued.

639. By reason of the foregoing, Defendants are liable to the estates of Decedent Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

TWELFTH CLAIM FOR RELIEF

Survival Action

640. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

641. As a direct and proximate result of the Defendants' wrongful conduct as outlined above, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, and loss of earnings as well as loss of ability to earn money prior to Decedent Plaintiffs' death.

642. The representative/administrator of Decedent Plaintiffs' estate brings this claim on behalf of Decedent Plaintiffs' estate and Decedent Plaintiffs' beneficiaries for damages.

643. The representative/administrator of Decedent Plaintiff's estate further plead all survival damages allowed by statute and law in the state or states in which the causes of action accrued.

644. By reason of the foregoing, Defendants are liable to the estates of Decedent Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

THIRTEENTH CLAIM FOR RELIEF

Loss of Consortium

645. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

646. At all relevant times stated herein, Plaintiffs spouses (hereinafter referred to as "Spouse Plaintiffs") and/or family members (hereinafter referred to as "Family Member Plaintiffs") have suffered injuries and losses as a result of Plaintiffs' injuries.

647. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

648. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

649. For all Spouse Plaintiffs, Plaintiffs allege his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

650. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

651. As a direct and proximate result of Defendants' wrongful conduct, Spouse

Plaintiffs and/or Family Member Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for all general, special and equitable relief to which Spouse Plaintiffs and/or Family Member Plaintiffs are entitled by law.

652. By reason of the foregoing, Defendants are liable to Spouse Plaintiffs and/or Family Member Plaintiffs for compensatory and punitive damages, in amounts to be proven at trial, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

FOURTEENTH CLAIM FOR RELIEF

Punitive Damages

653. Plaintiffs incorporate by reference each and every paragraph of this Master Complaint as if fully set forth herein and further allege as follows.

654. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiffs and other TRT product users and for the primary purpose of increasing Defendants' profits from the sale and distribution of TRT products. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

655. Prior to the manufacturing, sale, and distribution of TRT products, Defendants knew that said drugs were in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drugs presented a substantial and unreasonable risk of harm to the public, including Plaintiffs and as

such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using TRT products.

656. Despite their knowledge, Defendants, acting through their officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in TRT products and failed to warn the public, including Plaintiffs, of the extreme risk of injury occasioned by said defects inherent in TRT products. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of TRT products knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

657. Defendants' conduct was despicable and so contemptible that they would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiffs, entitling Plaintiffs to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray for relief and judgment against each of the Defendants as appropriate to each cause of action alleged and as appropriate to the particular standing of Plaintiff, as follows:

A. General damages in an amount that will conform to proof at time of trial;
B. Special damages in an amount within the jurisdiction of this Court and according to proof at the time of trial;
C. Loss of earnings and impaired earning capacity according to proof at the time of trial;
D. Medical expenses, past and future, according to proof at the time of trial;
E. For past and future mental and emotional distress, according to proof;
F. Damages for loss of care, comfort, society, and companionship in an amount within the jurisdiction of this Court and according to proof;

G. For punitive or exemplary damages according to proof;

H. Restitution, disgorgement of profits, and other equitable relief;

I. Injunctive relief;

J. Attorney's fees;

K. For costs of suit incurred herein;

L. For pre-judgment interest as provided by law; and

M. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all claims so triable.

Dated: March 17, 2015

Respectfully submitted,

/s/ Trent B. Miracle

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